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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Report

Bill Powers, Board President and Chair
Ruth Conroy, PharmD, Board Member
Robert Swart, PharmD, Board Member
Stan Goldenberg, RPh, Board Member

Including Report of the Meeting of December 12, 2006

A summary of the Enforcement Committee and Workgroup on E-Pedigree Meeting held December 12, 2006 is provided in **Attachment A,** near the back of this tab section.

1. Proposal to Develop an Ethics Course for Pharmacists Disciplined by the Board

NO RECOMMENDATION FROM THE COMMITTEE:

At the NABP District Meeting in October, Lorie Rice, Associate Dean, External Relations, of the UCSF School of Pharmacy, provided a presentation on her experiences in developing an ethics course for physicians. Ms. Rice did this in her role as a public board member of the Medical Board of California, following the Medical Board's determination that exiting ethics courses available for physicians are inadequate for ethical violations.

Ms. Rice will provide a presentation about establishing an ethics course for pharmacists at this board meeting.

A former executive officer of the Board of Pharmacy, Ms. Rice is willing to assist the board in developing a specialized course for pharmacists, similar to that developed for physicians, should this board be interested.

A copy of the Medical Board's regulation requirements specifying an ethics course as a condition of probation is provided in **Attachment 1**.

According to Ms. Rice, if the board were to develop a course, some of the issues the board would need to address would include:

(1) Who would be part of the task force to develop the components?
(2) What type of cases would be referred?

(3) What criteria would be needed to assess rehabilitation, redemption and contrition? Is there a willingness to change on the part of the licensee?

(4) How to build skills involving empathy, to ensure there is an opportunity to focus about the impact of the licensee's action on society and how it impacted patients?

(5) Follow up for each licensee is needed in 6 –12 months after course completion.

The Medical Board's course is set up for a maximum of 12 individuals, and during her presentation before the Enforcement Committee, Ms. Rice indicated it would seem feasible to have physicians and pharmacists in the same class. According to the Medical Board regulations, the class must be at least 22 hours.

The timeline needed by the Medical Board to develop its course was:

- 2002: Formation of the Task Force
- 2003: Public Comment periods
- 2004: Regulation Hearing
- 2005: Regulation became effective

2. **DEA Proposes 90-Day Rule for Prescriptions for Schedule II Controlled Substances**

FOR INFORMATION:

At the October Board Meeting, the board directed that staff prepare a letter supporting a proposed shift in DEA policy to allow prescribers to prescribe up to a 90-day supply of Schedule II controlled substances during a single office visit. This would allow prescribers to provide patients with three 30-day prescriptions at once, writing "do not fill" until a specified date on the additional prescriptions so that patients do not have to return simply to obtain a new prescription.

This proposal conforms to longstanding board policy to allow a prescriber to write multiple prescriptions for Schedule II drugs, with a "do not fill before" date entered on the additional prescriptions. However, federal interpretation of the federal law prohibited this practice – unless this revised interpretation is put into effect. (California law provides that a prescription for a Schedule II drug is valid for six months after the date it is written.)

A copy of the board's letter to the DEA, which was filed timely, is provided in **Attachment 2**.

3. **Report of the Workgroup on E-Pedigree:**

FOR INFORMATION:

At the December meeting, the committee heard presentations by EPCglobal, wholesalers AmerisourceBergen and Cardinal Health, and a vendor who makes RFID chips for container lids regarding the progress to implement electronic pedigrees into the drug distribution channel for California.

The Federal Food and Drug Administration provided a very brief update announcing that its December 1, 2006 planned implementation date for the PDMA to require paper pedigrees for all drugs distributed outside the authorized distribution channel (manufacturer to specific wholesaler to specific pharmacy) had been stopped by a federal judge's order. The FDA has not released its plans for reinstitution of paper pedigree requirements in light of this decision.

However, the FDA staff did commend the board for its ongoing efforts to institute electronic pedigree requirements for California as an important step in securing the drug distribution channel.

EPCglobal Update:

Bob Celeste of EPCglobal and Ron Bone of McKesson provided a presentation of where EPCglobal is with respect to its standards setting project for electronic pedigrees (**Attachment 3)**. At the time of the December meeting, EPCglobal was at the final stages of review for intellectual property rights. This was the final stage of review before the standards will be finalized. Completion of this review is expected in early January 2007.

In early January 2007, EPCglobal did announce finalization of the standard for electronic messaging (**Attachment 3)**. This is a major milestone for the implementation of electronic pedigree requirements. The new pedigree standard being developed will support item level serialization, electronic signatures, RFID using non-line of sight identification of pallets, cases or items, and inference.

A brief summary of EPCglobal's progress (as reported at the December meeting) in six areas is:

- Pedigree management use cases: objective: define all supply chain use cases, processes and information needs for use in creating pedigree messaging standards.
  Status: complete
- Pedigree messaging standards: objective: define a standard format for the pedigree-messaging standard that meets all federal and state requirements.
  Status: all standards work completed, prototype event was successful, technical review passed, intellectual property review underway
- Item level tagging: objective: define requirements for tagging pharmaceuticals at the item level; this includes requirements for manufacturing lines, distribution environments, transportation and retail environments.

Status: requirements complete. A high frequency technical work was formed to define the standard. High frequency and ultra high frequency pilots are underway to provide uniform air interface protocol at the item level. The high frequency standard is expected to completed in the 3rd quarter of 2007

- Serialization: objective: define requirements to be encoded on the electronic tag.
  Status: requirements completed. Two identifiers were identified for use (global trade item number (GTIN) and serialized shipping container number (SSCC)). The newly formed serialization group will address all remaining issues.
- Decommissioning: objective: define requirements for decommissioning tags as they leave the supply chain.
  Status: work to begin in January 2007, timeline is 6 months
- Track and trace: objective: define supply chain use cases, processes and information needs for sharing EPC-related data for forward and reverse logistics.
  Status: forward and reverse logistics processes and data exchanges completed, additional use cases to be addressed for 3rd party logistics and repackagers, product recall, data sharing strategy and guidelines are being developed.

EPCglobal's next steps will be to work through scenarios with the Board of Pharmacy, host a workshop for regulators from states with electronic pedigrees, and work with the formed industry adoption workgroup on serialization and time tagging issues. There will also be a regional summit for hospital issues on February 20.

Some of the issues that will be addressed by EPCglobal in the coming weeks will also involve use of NDC numbers involving controlled substances, which may be an issue for the DEA.

AmerisourceBergen

AmerisourceBergen Corporation (ABC) provided a presentation on a pilot it is initiating with IBM on electronic pedigrees. A copy of its press release and the PowerPoint presentation made during the board meeting is provided in **Attachment 4.**

IBM will provide a presentation of this system at today's board meeting.

AmerisourceBergen initiated this project in the belief that it has an opportunity to either be a leader or follower with respect to electronic tracking of drug products. In this regard, ABC has concerns with the size of the massive data that result from document-based pedigree that would be passed from one owner to the next as a drug product moves through the distribution channel. At each successive

step in the distribution channel, more data would be added to the database for each drug product, resulting in massive redundant data repositories, especially for those near the end of the distribution channel. There is little other use that a company will gain from such repositories, except for compliance with requirements.

Instead ABC is testing a "track and trace" model using technology from IBM. This system passes only a minimal amount of data as the product moves through the distribution channel, but that at any point, full data describing all items and all ownership can be quickly accessed and obtained by legitimate users. The system can also be accessed to obtain real time receiving and shipping information and for better management of inventory.

The ABC pilot will use ultra high frequency, 2-D bar codes and new high frequency tags on the drug products tested. Inference will be one component evaluated as products are shipped from manufacturer to wholesaler. Inference also will be evaluated on mixed totes of products from wholesalers to pharmacies. Board staff indicated at the Enforcement Meeting that these practices will be carefully reviewed for compliance with California requirements as the data is collected during the pilot.

Cardinal Health

Cardinal Health also provided a presentation on the results of its RIFD pilot run on ultra high frequency tagging of drug products from manufacturers through the supply chain (**Attachment 5**). The results of this study indicate that it is feasible for these tags to be added to product containers and be read throughout the system – under this pilot, they were read 95 to 97 percent of the time. Cardinal Health believes after some adjustment, readings near 100 percent can be accomplished, without disruption to the distribution channel.

Two different types of containers were tested, a round container and a square container. Tagging at various places (container, pallet, etc.) was also tested.

The results indicate:

- RFID tags can be successfully inlaid under existing FDA-approved pharmaceutical label stock.
- Packaging lines can be run at validated speeds while encoding and verifying RFID tag application.
- A single frequency (UHF) has the potential to work in critical points from pharmaceutical packaging to pharmacy receipt.
- No tag failures were encountered in any stage of the pilot.
- Item-level reads are not possible when cases are stacked on a pallet
- Unit read rates within mixed totes exceed 99 percent, but are not at 100 percent.
- 100 percent read rates at the case level on pallets are potentially obtainable

- Case read rates on a moving conveyor at shipping and receiving had read rates exceeding 99 percent.

The conclusion of the study was that RFID technology is feasible for tracking and tracing item level drugs in the pharmaceutical chain, but collaboration among the supply chain partners will be needed. Cardinal added that there has been more collaboration within the last six months among industry partners than in the last 18 months. Generation 2 UHF tags are superior in quality to the Gen 1 tags.

Demonstration of Technology for Tagging Products

Secure Packaging Systems provided a demonstration of a form of electronic tagging that would be positioned in the cap of a medicine container. Such tags could be beneficial for high cost biologicals and are in use in Europe. They are also capable of being developed with Braille markers and with color-coded caps.

During discussion mention was made about testing of biological products for stability following 48 hours of exposure to high frequency fields without any change in the medication inside the containers.

California Retailers Association

The California Retailers Association provided comments on behalf of chain store pharmacies in California in a letter dated December 1, 2006 **(Attachment 6)**.

The CRA's members are concerned that the 2009 date for implementation of electronic pedigrees in California will be impossible for the state's chain-store pharmacies because they are at the end of the distribution channel, and the technology put in place by manufacturers and wholesalers will need to be readable, adopted and installed in pharmacies before pharmacies can comply with the requirements.

Moreover, pharmacies are concerned that they will need to develop methods for storing and accessing electronic pedigrees, and these databases will be huge databases at the store level to manage and maintain. There are also concerns about whether there will be adequate staff available to install these systems and provide training to pharmacy staff about how to use them. These latter tasks cannot be initiated or planned for until the manufacturers and wholesalers fully implement and integrate the systems for electronic pedigrees that will be passed to the pharmacies.

The CRA stated that the pharmacies will need time beyond 2009 to be able to implement the standards.

4. Meeting Summary

A summary of the December 12, 2006 Enforcement Committee and Workgroup on E-Pedigree is provided as **Attachment A**.

5. Report on Enforcement Actions

A report of enforcement actions taken since July 1, 2006 is provided as **Attachment B**.

Attachment 1

Regulations Establishing an Ethics Course of the Medical Board of California

Medical Board of California - Division of Medical Quality
Ethics Course as Condition of Probation
Specific Language of Proposed Regulations

Adopt section 1358.1 in Article 3 of Chapter 2 of Division 13, Title 16 California Code of Regulations, to read as follows:

1358.1. Ethics Course Required as Condition of Probation.

A licensee who is required, as a condition of probation, to complete an ethics course shall take and successfully complete a professionalism program approved by the division that meets the requirements of this section.

(a) **Approved Provider.** The program provider shall be accredited by the Accreditation Council of Continuing Medical Education (ACCME), or by an entity qualified in Section 1337, to sponsor continuing medical education for physicians and surgeons and shall provide satisfactory written evidence that its professionalism program meets all of the requirements of this section.

(b) **Criteria for Acceptability of Program.**

(1) **Duration.** The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment. The provider shall identify the number of continuing medical education hours that will be credited upon successful completion of the program.

(2) **Faculty.** Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or

teaching institution. The provider shall submit with its application a curriculum vitae for each instructor for approval by the division or its designee.

(3) **Educational Objectives**. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.

(4) **Methods of Instruction**. The provider shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.

(5) **Content**. The program shall contain all of the following components:

(A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.

(B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of medicine in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.

(C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

(D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.

(E) Experiential exercises that allow the participants to practice concepts and newly developed skills sets they have learned during the didactic section of the class.

(F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact

(6) **Class Size**. A class shall not exceed a maximum of 12 participants.

(7) **Evaluation**. The program shall include an evaluation method that documents that educational objectives have been met—e.g. written examination or written evaluation—and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.

(8) **Records**. The provider shall maintain all records pertaining to the program, including a record of the attendance for each

participant, for a minimum of 3 years and shall make those records available for inspection and copying by the division or its designee.

(9) **Program Completion.** The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the division or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

(10) **Change in Course Content or Instructor**. The provider shall report to the division any change in course content or instructor within 30 calendar days after the date of that change.

NOTE: Authority cited: Section 2018, Business and Professions Code. Reference: Sections 2227, 2228, and 2229, Business and Professions Code.

Attachment 2

Board Letter to the DEA Supporting Writing Multiple Prescriptions for Schedule II Controlled Drugs for Dispensing to Patients Over a Three-Month Period

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

November 3, 2006

Deputy Administrator
Drug Enforcement Administration
Washington, DC 20537
Attention: DEA Federal Register Representative/ODL

RE: Docket No. DEA- 287N

Dear Sir or Madam:

Prior to the deadline for public comment of November 6, 2006, I am writing to express the qualified support of the California State Board of Pharmacy for the proposed rulemaking published in the Federal Register on September 6, 2006 (Docket No. DEA-287N). This proposed rule would modify 21 CFR Part 1306 to make clear that the prohibition on refills of Schedule II prescriptions stated by 21 USC § 829 does not prevent or prohibit a prescriber from writing multiple prescriptions for a Schedule II drug for a given patient on a given date, with instructions on the prescriptions indicating the earliest date on which each successive prescription may be filled (e.g., "do not fill before [30 days later/60 days later]").

As the rulemaking notice articulates, and as has long been the position of the California State Board of Pharmacy, this level of flexibility with regard to Schedule II prescribing practices will likely enhance the treatment of, and prevent the interruption of medication for, those patients with chronic pain, Attention Deficit Hyperactivity Disorder (ADHD), or other similar chronic or ongoing conditions being treated with Schedule II medications. The proposed rule better allows prescribers to exercise their professional judgments as to the appropriate interval between patient visits, allowing them where they deem it appropriate to prescribe up to a 90-day supply in three or more separate prescriptions.

The board supports this approach.

However, the board believes that this flexibility to permit prescribers to exercise professional judgment as to the appropriate interval between visits can and ought to be extended further. The board does not see the need to limit this judgment to a maximum of a 90-day supply, and would instead urge that no specific outer limit be placed on the total quantity of Schedule II drugs for which multiple prescriptions with "do not fill before" dates can be written on a given date. It ought to be left to prescribers, in consultation with their patients, to decide the appropriate intervals between visits.

Thank you for this opportunity to comment.

Sincerely,

William Powers

William Powers
President
California Board of Pharmacy

Attachment 3

EPCglobal's Presentation on the State of Pedigree and EPC/RFID Standards December 12, 2006 and January 2007 Press Release Regarding Finalization of Pedigree Standards

FOR IMMEDIATE RELEASE

For more information contact:

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EPCglobal Inc Ratifies Electronic Pedigree Standard

Provides Platform for Compliance for Pedigree Laws Requiring a Document-Based Approach

BRUSSELS, Belgium – January 11, 2007 – GS1 EPCglobal, the not-for-profit standards organization dedicated to driving global adoption of the Electronic Product Code (EPC) for supply chain excellence, today announced the ratification of the Electronic Pedigree Document specification.

The new standard was developed to help companies that are serializing products using EPC technology to comply with pedigree regulations, such as ones recently enacted in multiple states within the United States. The initial focus of the EPCglobal Electronic Pedigree Document standard was the Florida Drug Pedigree Act, but it was designed to be usable as a platform to support a wide variety of pedigree process applications.

The EPCglobal standard includes an ePedigree document schema as well as an ePedigree envelope schema that companies can use as a way of holding multiple ePedigrees together in a single document for electronic transmission. Industries currently using paper-based pedigree documents will find this standard a useful tool in the fight against product counterfeiting and for brand protection. The new standard will enable technology providers to create solutions that can provide document interoperability across the supply chain, from manufacturers to wholesalers to retailers.

"This effort marks an important step in ensuring trading partners have an interoperable way to exchange document-based pedigrees for pharmaceuticals and other products," said Chris Adcock, president of EPCglobal Inc. "We extend our thanks to the pharmaceutical supply chain professionals and solution providers who collaborated to develop and test the Electronic Pedigree Document standard. With this standard in place, supply chain participants can begin to comply with document-based pedigree regulations, like the Florida Drug Pedigree Act, without fear of serious interoperability issues."

Looking to the future, the EPCglobal Healthcare and Life Sciences (HLS) Industry Action Group has begun work to define the requirements to develop a full track and trace system based on the EPCIS (EPC Information Services) standard, which is expected in the first quarter of 2007. A full track and trace approach would enable the pedigree information to be shared upstream and downstream, as opposed to the limitation of simply passing it from trading partner to trading partner in one direction only. Track and trace has significant value for protecting the integrity of the supply chain and is seen as a more universal approach that can be applied globally and across multiple industries. Refinement and definition of this alternative approach is anticipated in 2007.

About EPCglobal Inc

EPCglobal Inc supports the global adoption of the Electronic Product Code as a global standard to enable accurate information and visibility about products in the supply chain. More information about EPCglobal Inc can be found at http://www.epcglobalinc.org.

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California Board of Pharmacy

State of Pedigree and EPC/RFID Standards

December 12, 2006

GS1 EPCglobal

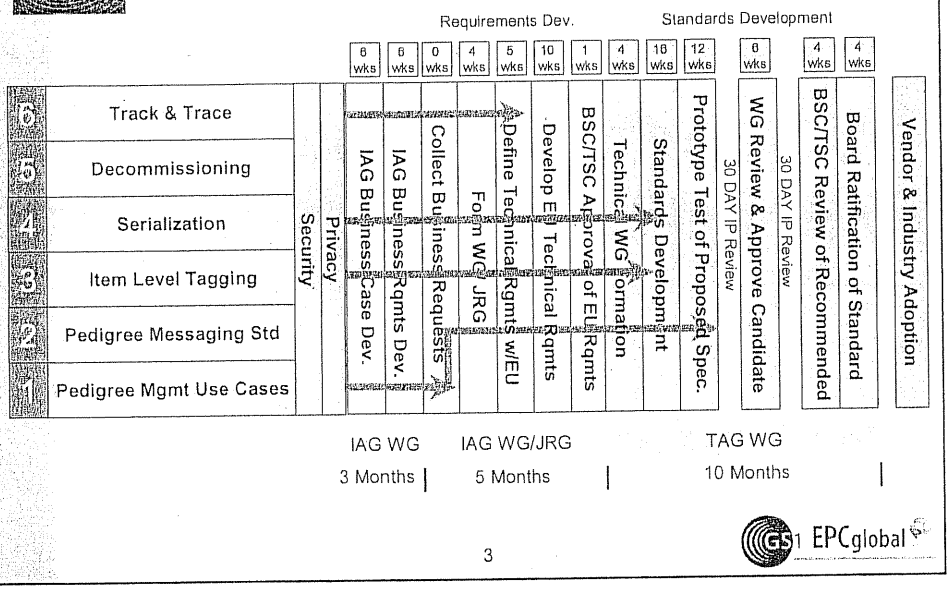
Agenda

- Standards Progress
- Pedigree Review Event

GS1 EPCglobal

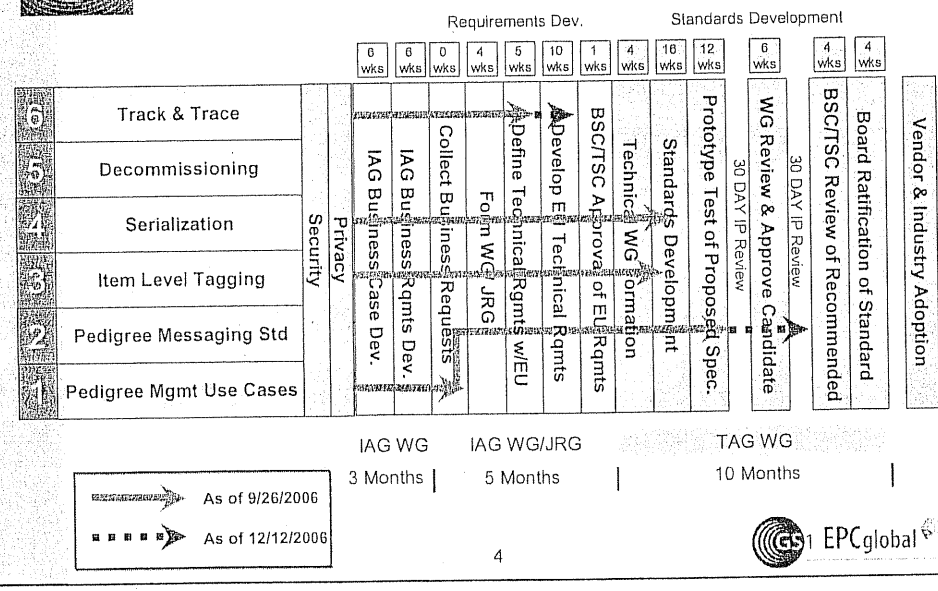
Standards Update

Last Report



Standards Update

Last Report



Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define all supply chain use cases, processes and information needs for use in creating a Pedigree Messaging Standard.

Status: Complete

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Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- All Standards work complete (Certification Requirements due 12/20/2006).
- Prototype event was successful.
- Passed Technical Review
- Intellectual Property Review period started
- **Ratification of standard anticipated 4Q/2006.**

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

Status:

- Requirements complete. Resulted in a High Frequency technical working group to define the standard.
- HF & UHF initiatives underway to provide uniform air interface protocol at item level.
- HF Standard expected 3Q07.

GS1 EPCglobal

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define requirements the EPC identifier to be encoded on an RFID tag.

Status:

- Requirements complete. Identified 2 GS1 Identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Joint group formed between EPCglobal Healthcare and Life Sciences Business Action Group (HLS) and GS1 Healthcare User Group (HUG).
- All remaining issues to be addressed by new Serialization group.

GS1 EPCglobal

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define requirements and/or guidelines for decommissioning tags as they leave the supply chain.

Status:

- HLS Work Group to be chartered & initiated January 2007
- Anticipate six month effort
- DEA interest in this capability is extremely high
- Solutions expected to span a mix of hardware, software and process responses
- Potential for this work to expand cross-industry

GS1 EPCglobal

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges have been completed
- Common vocabularies and location identifiers have been drafted
- Additional use cases to be addressed include:
  - 3rd Party Logistics Providers & Repackers
  - Product Recall
- Data Sharing Strategy & Guidelines are currently being addressed

GS1 EPCglobal

Pedigree Messaging Standard

Expected Ratification by end of 2006

GS1 EPCglobal

Review of Pedigree Standard
Features Supported

Feature	Required?	Support?
Item level serialization - Unique identification of each and every bottle of medication	No	Yes
Electronic Signatures - Ensures identity of Pedigree issuing company	Yes	Yes
RFID - Non Line of sight identification of Pallets, Cases or Items	No	Yes
Inference - Upon visual inspection, assuming content of containers (Pallets, Cases, Totes) based on Pedigree or Advanced Ship Notice (ASN)	No	Yes
Manufacturer initiated Pedigree - Manufacturer sends first pedigree to next participant in supply chain (as opposed to the first distributor)	No	Yes

GS1 EPCglobal

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Next Steps

- Walk Board of Pharmacy through Pedigree scenarios
- Host workshop for Regulators from States with electronic pedigree bills
- Industry Adoption WG formed
  - Working with Industry Associations on Serialization & Item Level Tagging issues
- Upcoming events:
  - EPCglobal Inc Joint Action Group Event (Jan 8-12, 2007)
  - Ongoing work on
    - Serialization
    - Item Level Tagging
    - Track and Trace
- Provide regular status updates to CA BoP

GS1 EPCglobal

Pedigree Review Event
Agenda

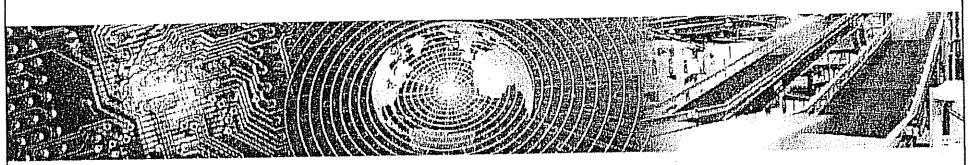
- Structure of the Pedigree Standard
- Implementation Guidelines Review
- Walkthrough seven Pedigree scenarios
- Pedigree Software Certification Process
- Pedigree Standard Revision Process

GS1 EPCglobal

Planned Activities
Regional Hospital Summits

Date	City	Event
January 23rd	Dallas	
February 20th	California	
March 1st	New Orleans	Healthcare Information and Management Systems Society (HIMSS)
March 13th	Boston	
April 17th	Chicago	
May 10th	Washington D.C.	American Hospital Association (AHA)

GS1 EPCglobal



Questions?

GS1 EPCglobal

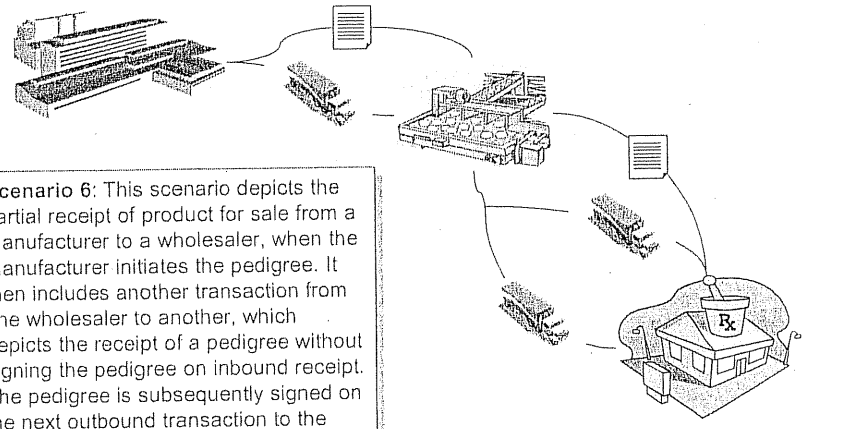
Additional Slides

GS1 EPCglobal

EPCglobal Pedigree Prototype Event
Scenarios

- **Scenario 1**: This scenario depicts the pedigree flow for the sale of a serialized product from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler then sells and ships one of the product items to a pharmacy DC.
- **Scenario 2**: This scenario depicts the sale of a non-serialized product from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 3**: This scenario depicts the sale from a wholesaler to a retail pharmacy DC, when a paper pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 4**: The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. The repack pedigree contains the pedigree for the source product used to create the repack products ·
- **Scenario 5**: This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.
- **Scenario 6**: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.
- **Scenario 7**: This scenario depicts the pedigree flow for the sale of a non-serialized product from a manufacturer to a wholesaler, when the wholesaler initiates the pedigree. The wholesaler then sells and ships the product to a pharmacy DC, then the pharmacy DC returns the product to the wholesaler. Then the wholesaler sells and ships the product to another pharmacy DC. This pharmacy DC also returns the product to the wholesaler.

EPCglobal Pedigree Prototype Event
Sample Scenario



Scenario 6: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.

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GS1 EPCglobal

Attachment 4

AmeriscourceBergen's Presentation at the December 12, 2006 Meeting and Press Release Regarding Pilot Testing of Electronic Pedigree

AmerisourceBergen

News Release

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AMERISOURCEBERGEN ANNOUNCES INNOVATIVE TRACK AND TRACE PROGRAM FOR THE PHARMACEUTICAL SUPPLY CHANNEL

Prepares California Launch of Unique Pilot Developed in Conjunction with IBM and VeriSign

Valley Forge, PA November 13, 2006-- AmerisourceBergen Corporation (NYSE: ABC) today announced at the NACDS and HDMA RFID Healthcare Industry Adoption Summit being held this week in Washington, DC, an innovative Track and Trace Program that it believes will ultimately benefit the entire pharmaceutical supply channel. AmerisourceBergen has been a leader in protecting the integrity of the pharmaceutical supply channel, first by pledging over one year ago to purchase 100 percent of its pharmaceutical and other products directly from the product manufacturer, and now by launching a unique Track and Trace initiative which will utilize RFID and Electronic Product Code Information System (EPCIS) technology to track and trace products throughout the entire distribution process. AmerisourceBergen plans to formally launch the Track and Trace pilot program at its largest distribution center in California by the end of 2006.

In the pilot, AmerisourceBergen will use IBM's RFID middleware and embedded software on readers to read RFID tags currently used by certain pharmaceutical manufacturers as those products enter the distribution center. The unique product ID from each RFID tag will be electronically stored in IBM's EPCIS, which will be the platform for secure electronic communications back to the product's manufacturer. This secure information exchange will allow AmerisourceBergen and its trading partners to work collaboratively to share transaction information and further secure the supply channel.

As new orders come into the AmerisourceBergen distribution center, the RFID system can monitor product placed in shipping totes as they move through the picking, packing, and shipping processes. As each tote leaves the distribution center the EPCIS software will record

the time and location of each unit leaving the premises as well as its intended destination so that AmerisourceBergen has a complete record of the history of all RFID tagged drugs.

"The advantage of using the RFID and EPCIS system is that the information regarding the product's journey through the supply chain is stored in a manner that is useful for a number of different applications," said Shay Reid, AmerisourceBergen Vice President for Integrated Solutions. "Once the RFID tags have been read and the data has entered the EPCIS, the system can be queried to build a product pedigree for customers on demand, to provide real time receiving and shipping information to manufacturers as well as to more closely track both inventory and product demand."

"With IBM's extensive experience in designing and deploying RFID solutions, I can say that distributors like ABC will have a great advantage supporting customers through offering unique track and trace data," said Paul Chang, RFID/Pharma Executive, IBM Software Group. "And in an industry that lives depend on, IBM is providing the technology that will lead to a more efficient, safer, and more secure supply chain."

The next step in the pilot program will be to connect AmerisourceBergen's EPCIS directly to other business partner EPCIS systems and to select pharmaceutical manufacturer systems. In the first calendar quarter of 2007, VeriSign will provide services to support the deployment of technology and software necessary to enable AmerisourceBergen to communicate and authenticate transactions with its business partners while also providing the capability to query across multiple EPCIS systems.

Jeff Richards, vice president and general manager of VeriSign Intelligent Supply Chain Services stated, "AmerisourceBergen's innovative pilot will create unprecedented, direct electronic data connectivity to its trading partners. This level of data sharing and connectivity is a critical step towards allowing the pharmaceutical industry to trace the historical path of a particular product through the supply chain, which will add a level of security and efficiency to the pharmaceutical distribution process."

As AmerisourceBergen tests its Track and Trace pilot program, it intends to continue to supply electronic pedigrees in the state of Florida to those wholesale customers that require them under the state's current drug safety laws. Under the pedigree program, customers are charged fees that allow the Company to recover the cost of generating the pedigrees. The Company intends to offer its nationwide wholesale customers the same electronic pedigree program in support of the Prescription Drug Marketing Act (PDMA), which goes into full effect on December 1, 2006. The PDMA rule requires wholesalers who are not "authorized distributors of

record" to provide a pedigree showing chain-of-ownership back to the manufacturer when selling the drugs to pharmacies.

About AmerisourceBergen

AmerisourceBergen (NYSE:ABC) is one of the world's largest pharmaceutical services companies serving the United States, Canada and selected global markets. Servicing both pharmaceutical manufacturers and healthcare providers in the pharmaceutical supply channel, the Company provides drug distribution and related services designed to reduce costs and improve patient outcomes. AmerisourceBergen's service solutions range from pharmacy automation and pharmaceutical packaging to pharmacy services for skilled nursing and assisted living facilities, reimbursement and pharmaceutical consulting services, and physician education. With more than $61 billion in annual revenue, AmerisourceBergen is headquartered in Valley Forge, PA, and employs more than 14,000 people. AmerisourceBergen is ranked #27 on the Fortune 500 list. For more information, go to www.amerisourcebergen.com.

Forward Looking Statement

This news release may contain certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances. Actual results may vary materially from the expectations contained in the forward-looking statements. The forward-looking statements herein include statements addressing management's views with respect to future financial and operating results and the benefits, efficiencies and savings to be derived from the Company's integration plan to consolidate its distribution network. The following factors, among others, could cause actual results to differ materially from those described in any forward-looking statements: competitive pressures; the loss of one or more key customer or supplier relationships; customer defaults or insolvencies; changes in customer mix; supplier defaults or insolvencies; changes in pharmaceutical manufacturers' pricing and distribution policies or practices; adverse resolution of any contract or other disputes with customers (including departments and agencies of the U.S. Government) or suppliers; regulatory changes; changes in U.S. government policies (including reimbursement changes arising from the Medicare Modernization Act); declines in the amounts of market share rebates offered by pharmaceutical manufacturers to the PharMerica Long-Term Care business, declines in the amounts of rebates that the PharMerica Long-Term Care business can retain, and/or the inability of the business to offset the rebate reductions that have already occurred or any rebate reductions that may occur in the future; any disruption to or other adverse effects upon the PharMerica Long-Term Care business caused by the announcement of the Company's agreement to combine the PharMerica Long-Term Care business with the institutional pharmacy business of Kindred Healthcare, Inc. into a new public company that will be owned 50% by the Company's shareholders (the "PharMerica LTC Transaction"); the inability of the Company to successfully complete the PharMerica LTC Transaction; fluctuations in market interest rates; operational or control issues arising from the Company's outsourcing of information technology activities; the Pharmaceutical Distribution segment's ability to continue to successfully transition its business model to fee-for-service; success of integration, restructuring or systems initiatives; fluctuations in the U.S. dollar – Canadian dollar exchange rate and other foreign exchange rates; economic, business, competitive and/or regulatory developments in Canada, the United Kingdom and elsewhere outside of the United States; acquisition of businesses that do not perform as we expect or that are difficult for us to integrate or control; and other economic, business, competitive, legal, regulatory and/or operational factors affecting the business of the Company generally. Certain additional factors that management believes could cause actual outcomes and results to differ materially from those described in forward-looking statements are set forth (i) in Item 1 (Business) under the heading "Certain Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2005 and elsewhere in that report and (ii) in other reports filed by the Company pursuant to the Securities Exchange Act of 1934.

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AmerisourceBergen

California Board of Pharmacy Update

Dec. 12, 2006

Shay Reid
Vice President, Integrated Solutions

- Primary Business:
  - Service both pharmaceutical manufacturers and healthcare providers in the pharmaceutical supply channel.
  - Provide pharmaceutical distribution and related services designed to reduce cost and improve patient outcomes.
  - More than 40 distribution centers throughout the US and other international locations.
  - 100% of ~11,500 Rx Products are Purchased Directly from One of 400 Different Manufacturers.

- California Presence
  - Three (3) state of the art distribution centers
  - Approximately 800 employees
  - Deliver to more than 3,000 California

California's Call to A New Frontier on March 16, 2006:

> *"We stand today on the edge of a new frontier,...a frontier of unknown opportunities and paths, a frontier of unfulfilled hopes and threats.... The new frontier...is not a set of promises, it is a set of challenges. It sums up not what I intend to offer the American people, but what I intend to ask of them."*
>
> John F. Kennedy – 1960 Presidential Campaign

California Asked the Pharmaceutical Industry For:

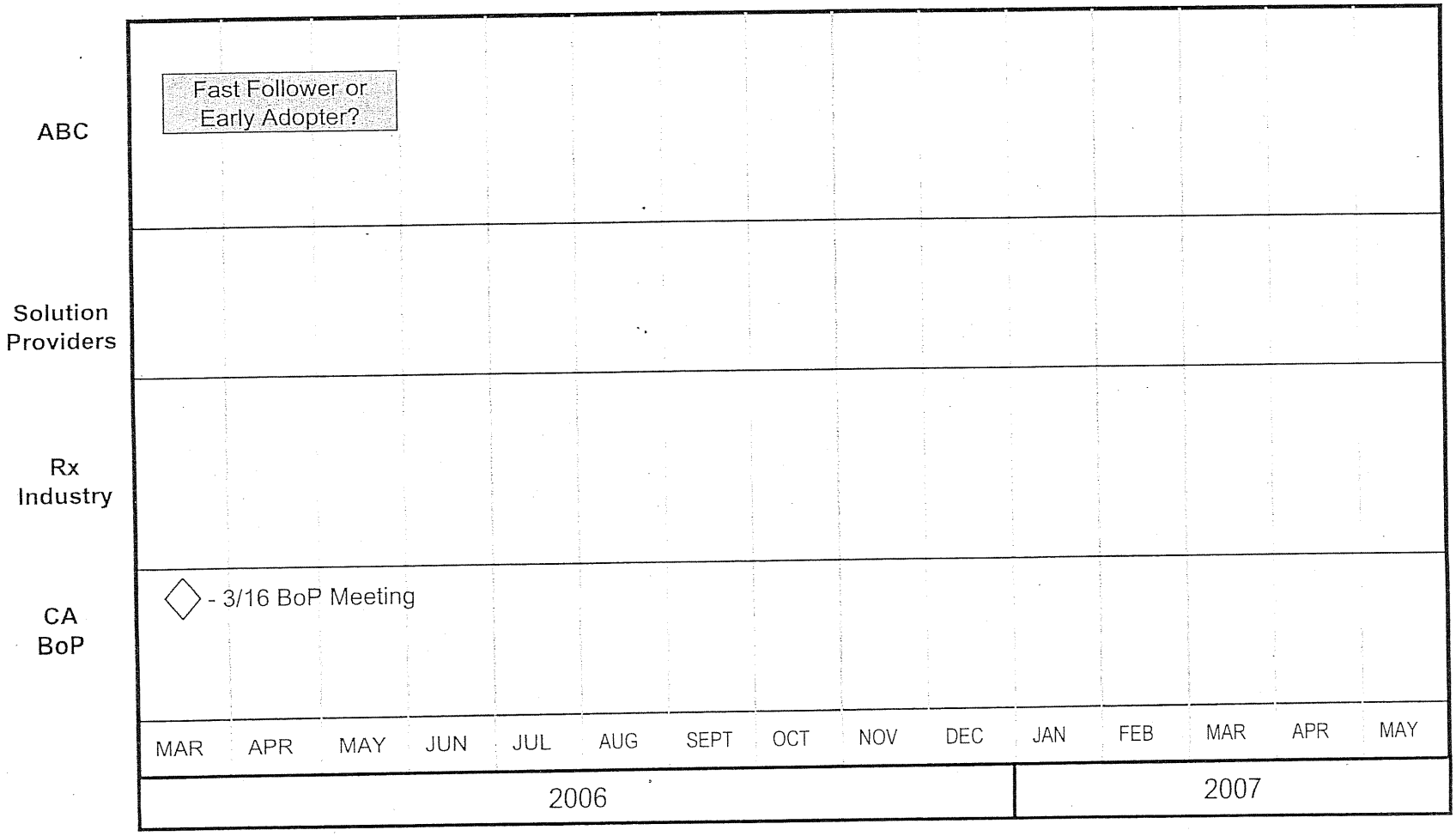
"Innovation to create a vision using available technology."

"Pioneers that can pave the way for others."

"Collaboration focused on patient safety."

"A milestone plan for adoption."

ABC's Decision:



ABC Choice – Fast Follower or Early Adopter?

FAST FOLLOWER	EARLY ADOPTER
Wait for Answers	Develop a Vision
Standards Victim	Collaboration
Project Team	Cross Functional Task Force
Investment in Solution	Investment in Future
Compressed Project Schedule	Design – Build – Evaluate Cycle

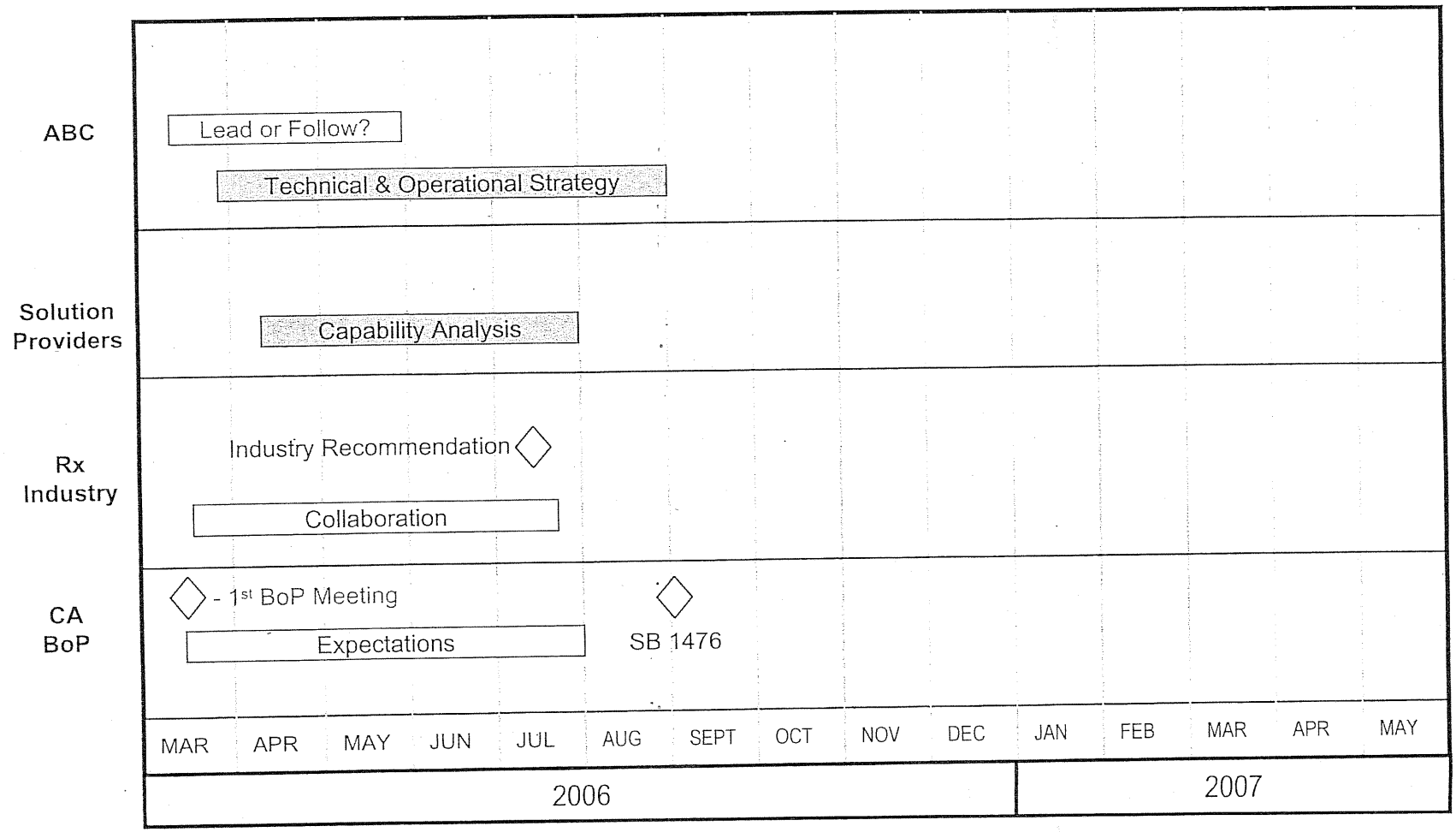
ABC Decided To Answer California's Call for Early Adopters to:

- Innovate
- Pioneer
- Collaborate
- Plan

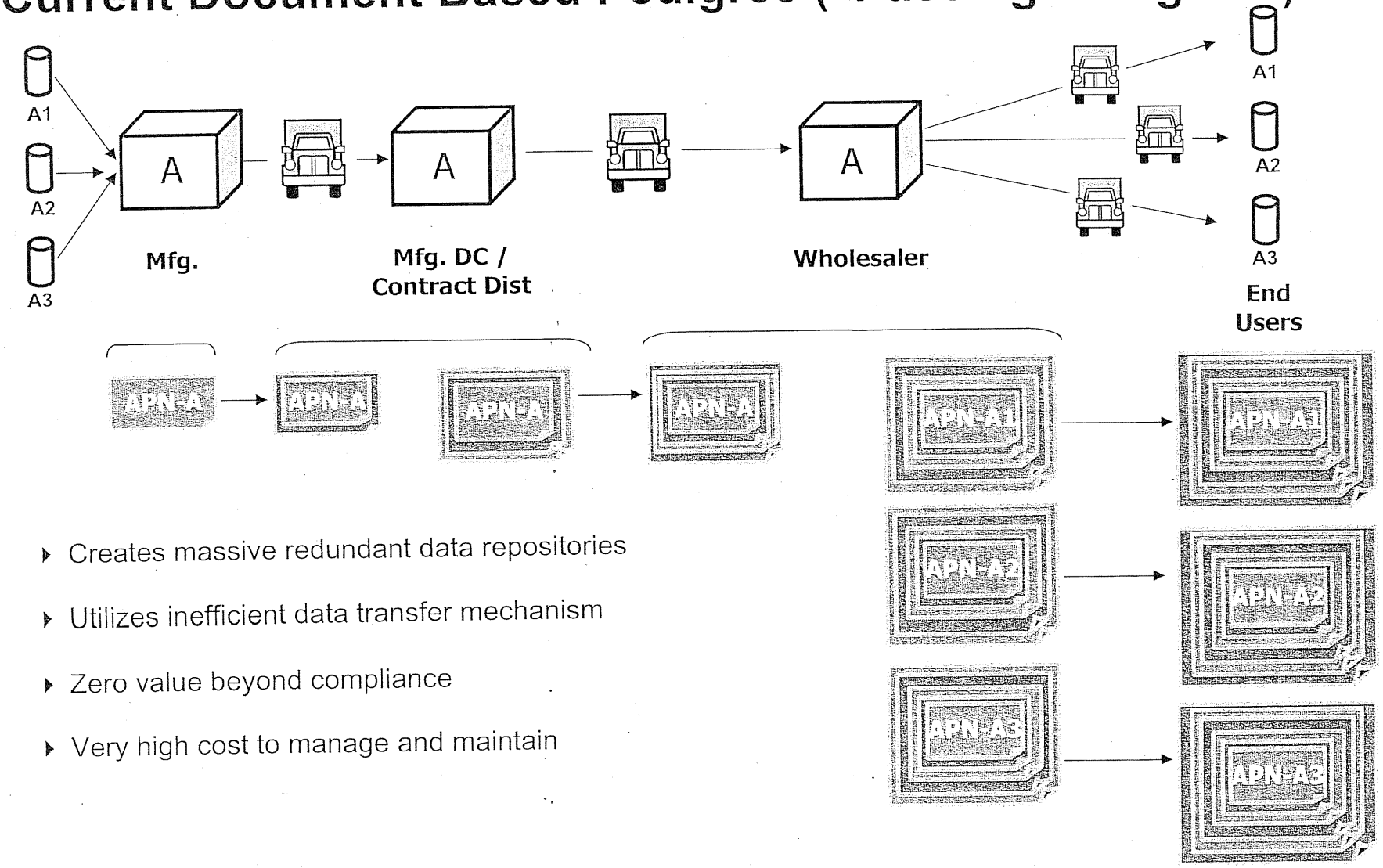
Toward a Focus of Greater Patient Safety

- Right Product
- Right Time
- Right Place
- Right Quantity
- Reasonable Cost

ABC's Plan to Innovate:

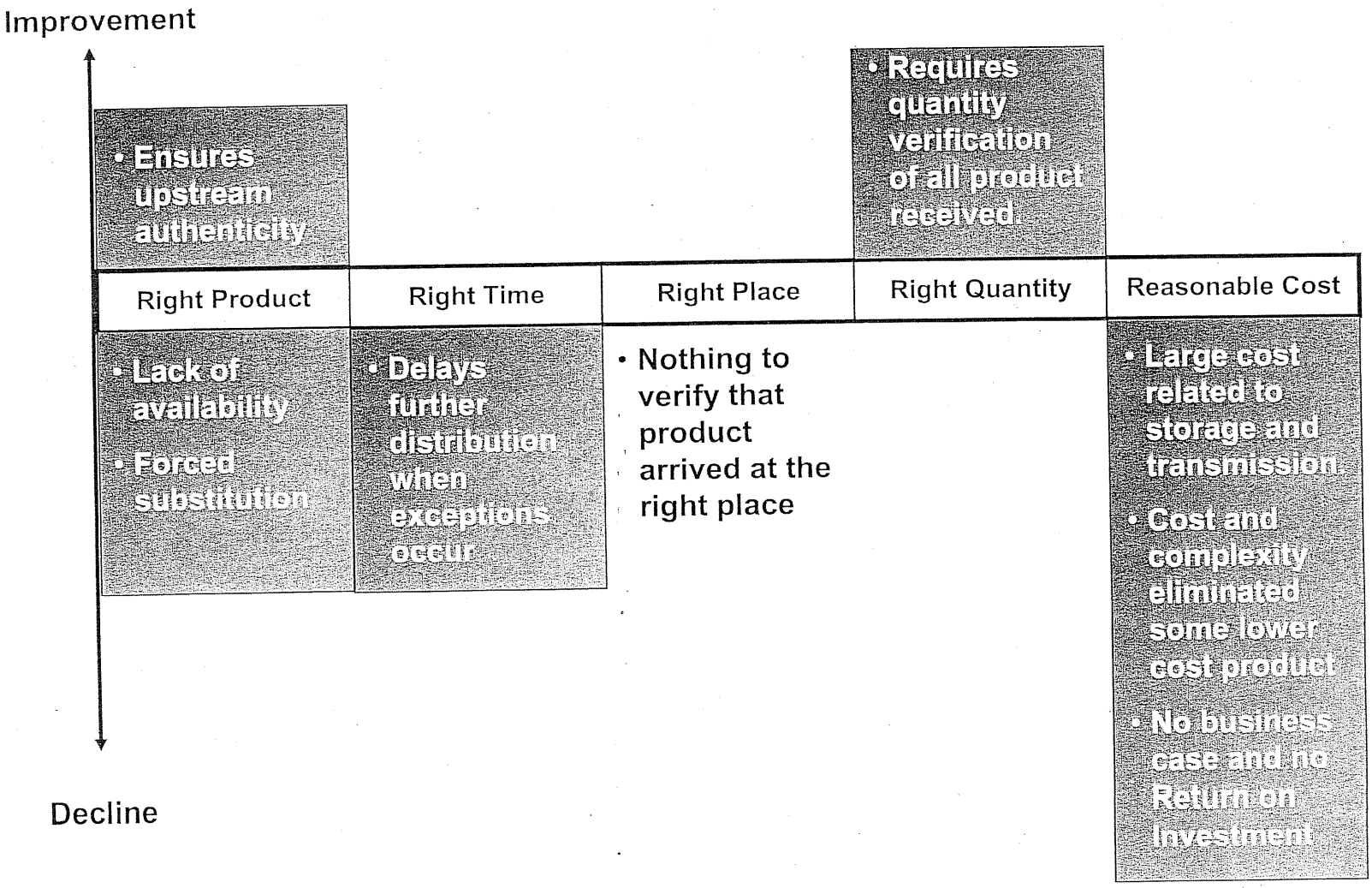


Current Document Based Pedigree ("Passing Pedigree"):

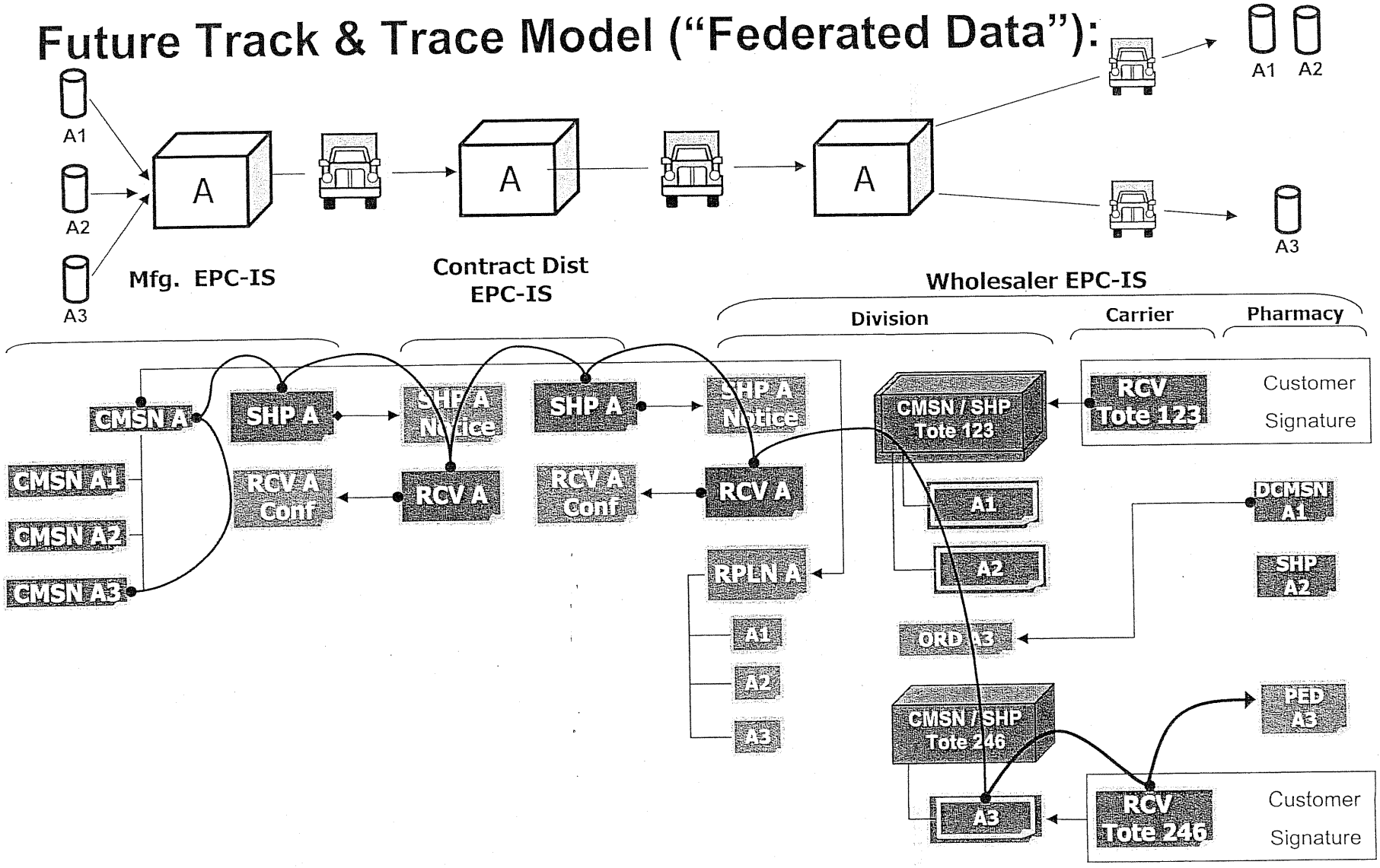


- Creates massive redundant data repositories
- Utilizes inefficient data transfer mechanism
- Zero value beyond compliance
- Very high cost to manage and maintain

Current "Passing Pedigree" – Patient Safety Test:

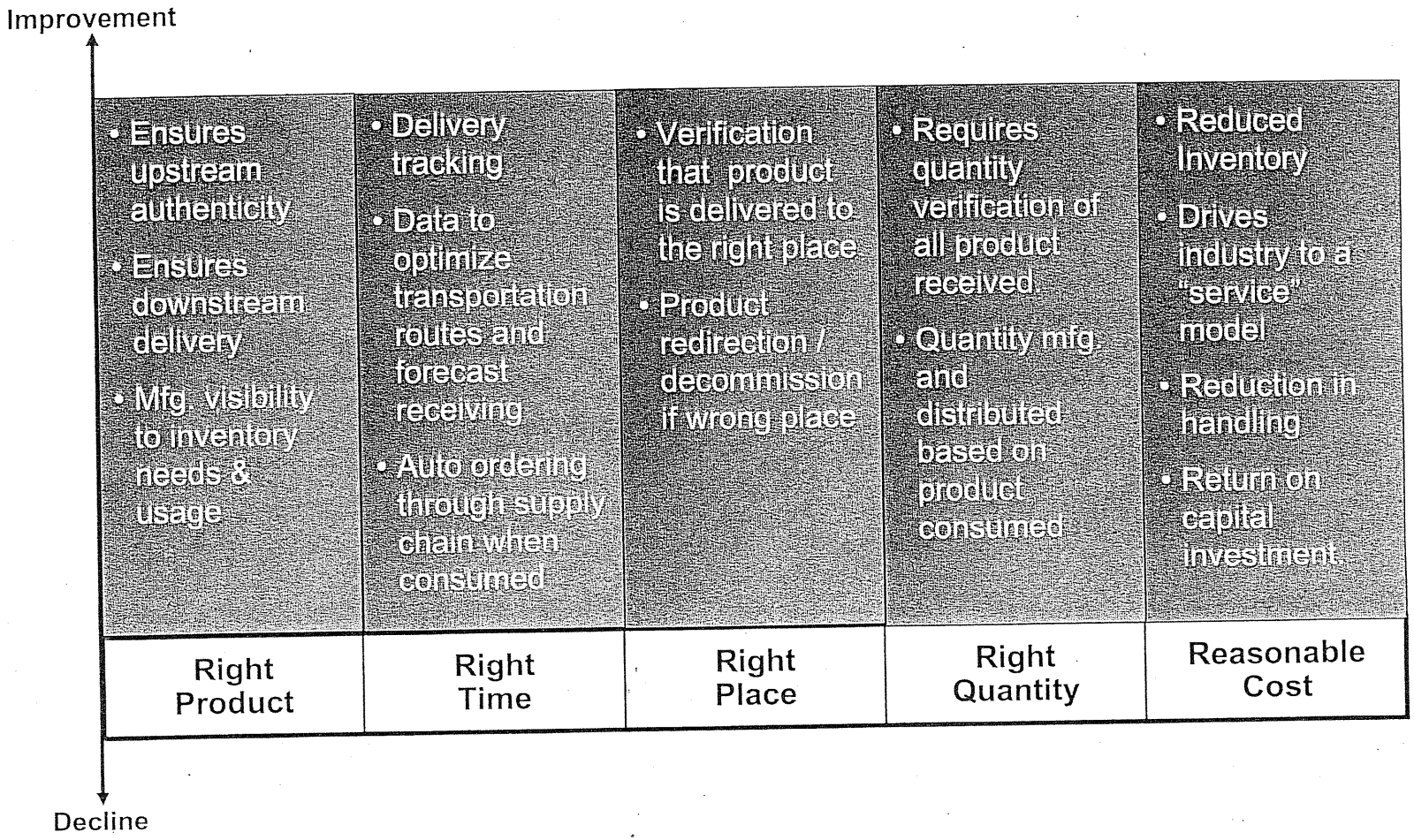


Future Track & Trace Model ("Federated Data"):

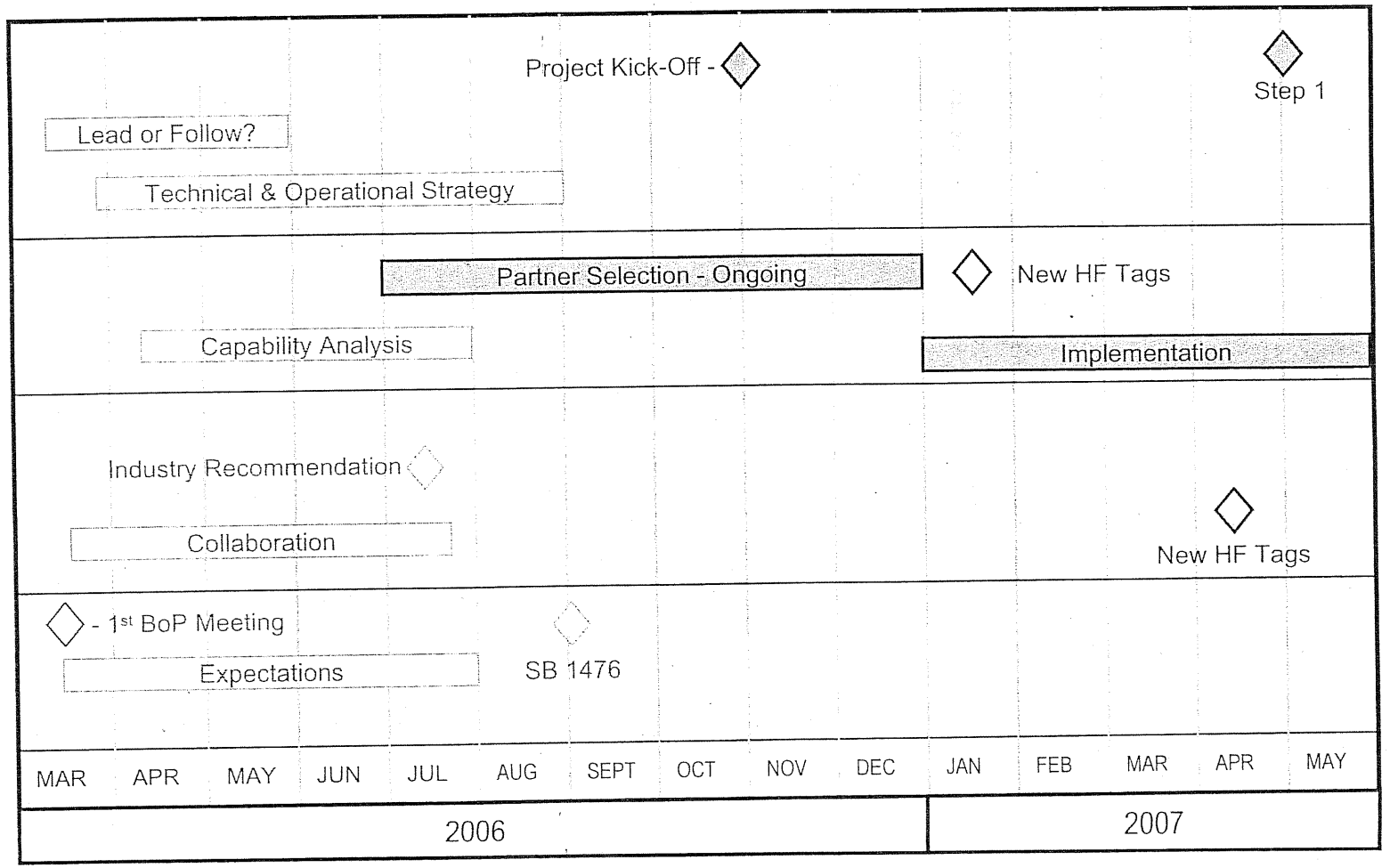


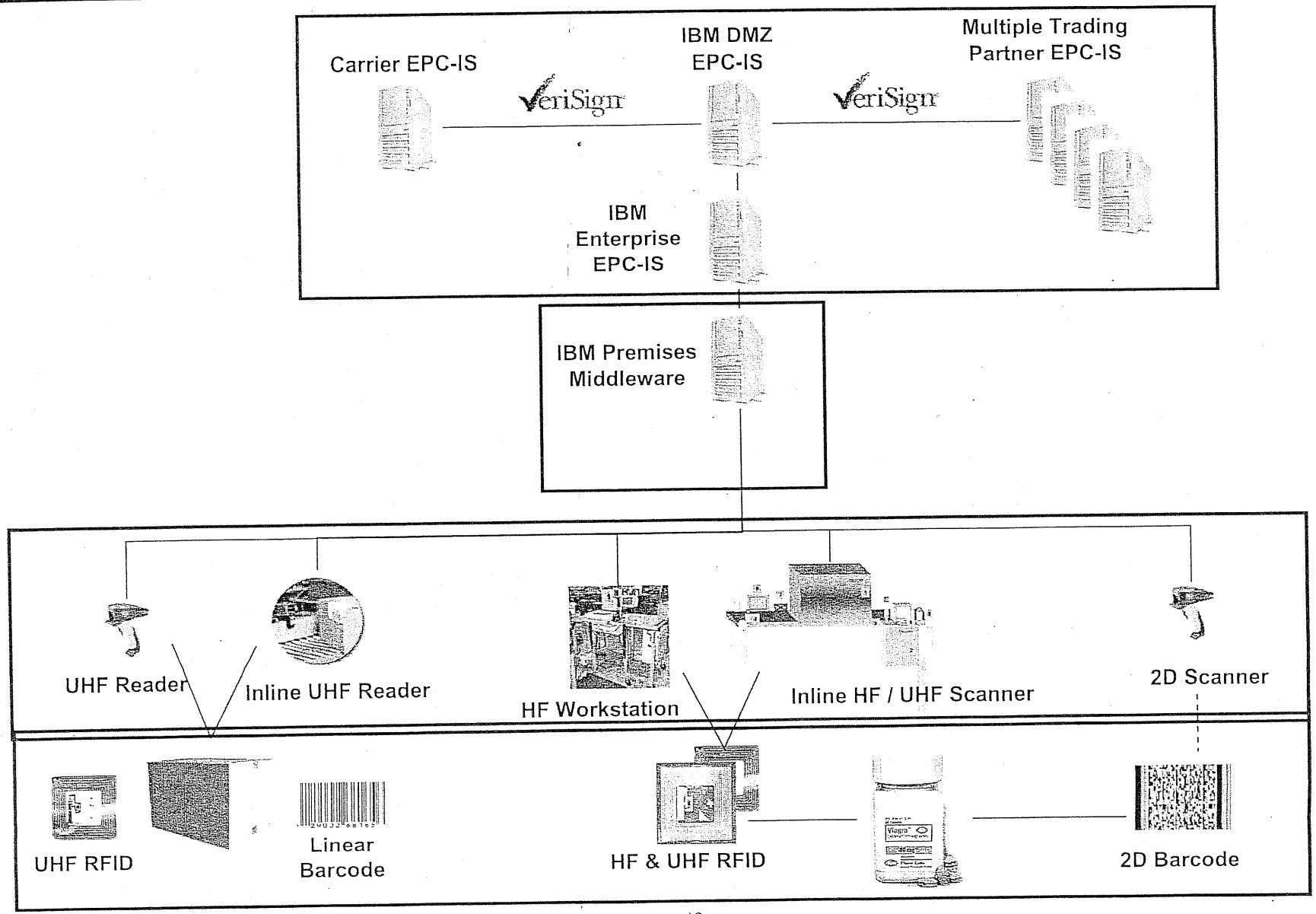
AmerisourceBergen

Future Track & Trace Model – Patient Safety Test:

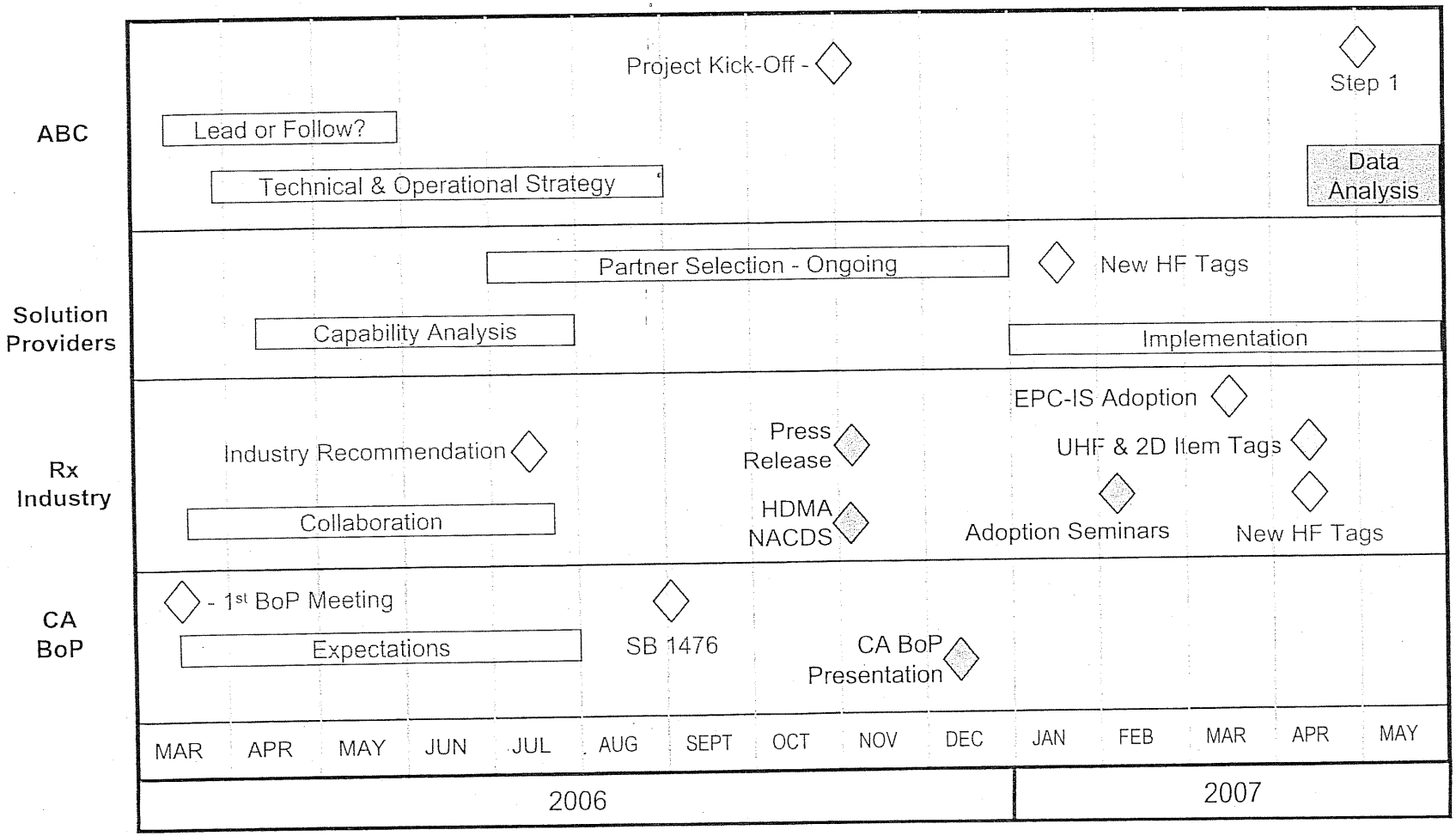


ABC's Plan to Pioneer:




Carrier EPC-IS
IBM DMZ EPC-IS
Multiple Trading Partner EPC-IS
VeriSign
VeriSign
IBM Enterprise EPC-IS
IBM Premises Middleware
UHF Reader
Inline UHF Reader
HF Workstation
Inline HF / UHF Scanner
2D Scanner
UHF RFID
Linear Barcode
HF & UHF RFID
2D Barcode

ABC's Plan to Collaborate:



ABC Appreciates CA BoP Approach:

- A Cautious Drive Toward Industry Action
- Electronic Track & Trace Includes Entire Supply Chain
- Unique Item Level Identification
- Non Prescriptive Technology
- Flexibility For Inference

Questions?

Attachment 5

Cardinal Health's Presentation to the December 12, 2006 Enforcement Meeting and Press Release on the Results of Its Electronic Pedigree Pilot Study

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FOR IMMEDIATE RELEASE

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CARDINAL HEALTH RELEASES RFID PILOT RESULTS

Test data shows promise and gaps of the technology that will affect widespread adoption across pharmaceutical industry

DUBLIN, Ohio, Nov. 14, 2006 — Cardinal Health, Inc., the leading provider of products and services supporting the health-care industry, today announced the results from the first end-to-end test of a technology that could further improve the safety and efficiency of the nation's pharmaceutical supply chain.

The pilot program tested whether ultra-high frequency (UHF) radio frequency identification (RFID) tags could be applied, encoded and read at normal production speeds during packaging and distribution of pharmaceuticals. Verifying the authenticity of medications along each step of the distribution process adds an additional layer of security to lessen the chance of counterfeit pharmaceuticals entering the supply chain. It is also hoped that RFID data could improve efficiencies in the supply chain.

"Cardinal Health's test of RFID under real-world conditions has demonstrated that the technology has real promise to provide an added layer of safety," said Renard Jackson, vice president and general manager of global packaging services for Cardinal Health. "While our pilot demonstrated that using UHF RFID technology at the unit, case and pallet level is feasible for track and trace purposes, a great deal of additional work needs to be undertaken by stakeholders across the industry to address significant challenges including global standards, privacy concerns and the safe handling of biologics. Until those challenges are addressed, direct distribution of medicine continues to be the best near-term approach to maintain the highest levels of security and efficiency in the pharmaceutical supply chain."

RFID Labeling and Online Encoding

Data collected from the pilot suggest that it is feasible for RFID tags to be inlaid into existing FDA-approved pharmaceutical label stock, and the tags can be applied and encoded on packaging lines at normal operational speeds. Online encoding yields were 95 percent to 97 percent, and fine tuning of the process is expected to produce yields that approach 100 percent. The RFID tag application and encoding requires minimal adjustments to current labeling and packaging lines.

- more -

RFID Read Rates

Unit-level read rate data varied widely depending on the locations and type of reading stations throughout the supply chain. Highly reliable unit-level read rates in excess of 96 percent were found when reading individual cases one at a time and when reading units mixed with other products in tote containers prepared for delivery to a pharmacy. However, as expected, unit-level read rates were not found to be reliable when attempting to read units within a full pallet of product.

While not 100 percent in all situations, case-level data were found to be more reliable during full pallet reads. The combination of business process changes, and further hardware tuning is expected to improve the reliability of case tag reads to 100 percent, however further tests are needed to prove this hypothesis.

In preparation for delivery to the pharmacy, individual bottles are "picked" and placed in tote containers with other products that did not have RFID tags. The unit-level read rates from the tote containers being read during the quality control phase were acceptable for track and trace. Additional unit-level read rates while the product was in the tote containers were not found to be reliable during subsequent reading stations at the shipping dock of the distribution center and the receiving doors at the pharmacy.

Pilot Program Read Rate Data

Cardinal Health's RFID pilot program tested many different possible reading stations throughout the supply chain. While the company expected that some reading stations would not achieve acceptable read rates, the lack of hard data in the marketplace led program planners to measure all possible scenarios. Read rate data for item- and case-level tags are included in the chart below.

	Item-Level Read Rates		Case-Level Read Rates	
	Product A	Product B	Product A	Product B
Unit Encoding Yield During Packaging	97.7%	94.8%	NA	NA
Unit to Case Aggregation	96.9%	99.7%	91.8%	100%
Case to Pallet Aggregation*	56.4%	80.8%	100%	99.7%
Shipping Pallet from Packaging Facility*	9.2%	14.3%	82.3%	100%
Receiving Pallet at Distribution Center*	7.8%	9.5%	76.3%	100%
Receiving Case at Distribution Center	92.1%	97.1%	99.4%	100%
Reading Totes at Distribution Center	NA	99.5%	NA	
Shrink Wrap Tote Carts at Distribution Center	NA	64.1%	NA	
Shipping from Distribution Center	NA	46.1%	NA	
Receiving at Pharmacy	NA	85.8%	NA	

RFID Pilot Program Conclusions

Overall data collected by Cardinal Health supports the theory that RFID technology using UHF as a single frequency at the unit, case and pallet levels is feasible for track and trace. However, several challenges remain before it can be adopted industry-wide. Some of those challenges include:

- Technology and process improvements to achieve:
  - Case-level reads in excess of 99 percent at all case reading stations;
  - Unit-level read rates in excess of 99 percent when reading from tote containers at the distribution center and pharmacy locations;
- Allowing unit-level "inference" to become acceptable practice in the normal distribution process at stages where unit-level read rates are unreliable, but case level reads approach 100 percent (*Three stages marked in chart above);
- Barcode technology to be used as complementary and redundant technology to RFID;
- Management of the cost impact to implement and sustain the technology; and
- Improved collaboration across the industry to identify opportunities to significantly improve efficiency.

Pilot Program Background

In conducting the industry's first end-to-end pilot program, Cardinal Health used new technology to place RFID tags on the labels of brand-name solid-dose prescription drugs, then encoded the electronic product code (EPC) standard data at the unit, case and pallet levels during the packaging process. The products were shipped to a Cardinal Health distribution center in Findlay, Ohio, where the data was read and authenticated as products were handled under typical operating conditions. Normal procedures were enhanced with RFID hardware and software from Alien Technology Corporation and IBM along with project management support from VeriSign.

From Findlay, the tagged product was sent to a pharmacy to further test read rates and data flow using the same technology as the distribution center. The product dispensed to patients was not in the RFID packaging.

The company launched the pilot in February and completed the test in the fall. In addition, Cardinal Health is working with Pfizer on a separate RFID pilot to authenticate Viagra® shipments at its Findlay facility.

About Cardinal Health

Headquartered in Dublin, Ohio, Cardinal Health, Inc. (NYSE: CAH) is an $81 billion, global company serving the health-care industry with a broad portfolio of products and services. Through its diverse offerings, Cardinal Health delivers health-care solutions that help customers reduce their costs, improve safety and productivity, and deliver better care to patients. The company manufactures, packages and distributes pharmaceuticals and medical supplies, offers a range of clinical services and develops automation products that improve the management and delivery of supplies and medication for hospitals, physician offices and pharmacies. Ranked No. 19 on the Fortune 500, Cardinal Health employs more than 55,000 people on six continents. More information about the company may be found at www.cardinalhealth.com.

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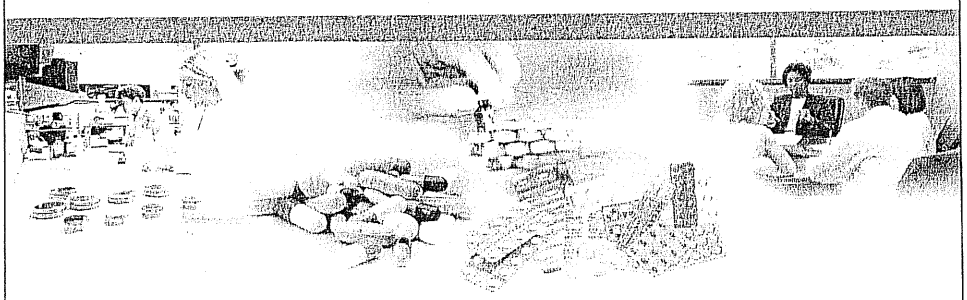
Except for historical information, all other information in this news release consists of forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied. The most significant of these uncertainties are described in Cardinal Health's Form 10-K, Form 10-Q and Form 8-K reports (including all amendments to those reports) and exhibits to those reports, and include (but are not limited to) the following: competitive pressures in its various lines of business; the loss of one or more key customer or supplier relationships or changes to the terms of those relationships; changes in the distribution patterns or reimbursement rates for health-care products and/or services; the results, consequences, effects or timing of any inquiry or investigation by or settlement discussions with any regulatory authority or any legal and administrative proceedings, including shareholder litigation; difficulties in opening new facilities or fully utilizing existing capacity; the costs, difficulties and uncertainties related to the integration of acquired businesses; and general economic and market conditions. Except to the extent required by applicable law, Cardinal Health undertakes no obligation to update or revise any forward-looking statement.

CardinalHealth

December 12, 2006



Cardinal Health RFID Pilot Results

Julie Kuhn
Julie.Kuhn@cardinal.com

Agenda

- RFID Pilot
  - Overview
  - Results
  - Conclusion

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Pilot Overview

- Background
  - In 2004
    - Adoption of direct-distribution model
    - Develop an offering of authentication and track & trace technologies aimed at further securing supply-chain
    - Participated in first industry-wide RFID testing (Jumpstart 1)
  - In 2005
    - Collaborated with industry in RFID planning process (Jumpstart 2)
    - Began integrated effort between manufacturing / packaging and distribution businesses to develop an RFID solution
    - Solicited and received proposals from technology leaders
      - » Hardware
      - » Software (Middleware & Pedigree)
      - » Project Management
    - Met with various potential customers to gain knowledge on brand security/ RFID internal efforts
  - In 2006
    - Executed pilot

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RFID Pilot Objectives

- Optimize tagging operations
  - Considerations for inbound bulk drum tagged by manufacturer
  - Integrate printed component tag application into packaging operations
- Gather production data for internal and external publication
  - Determine read rate accuracy
  - Determine impact to current production processes & opportunities for improvement
  - Evaluate Cost impact of multiple facility scale-up
  - Establish infrastructure to provide feedback to manufacturers
  - Share results with legislative bodies regarding readability and possible effects on current cGMP/ regulatory practices.

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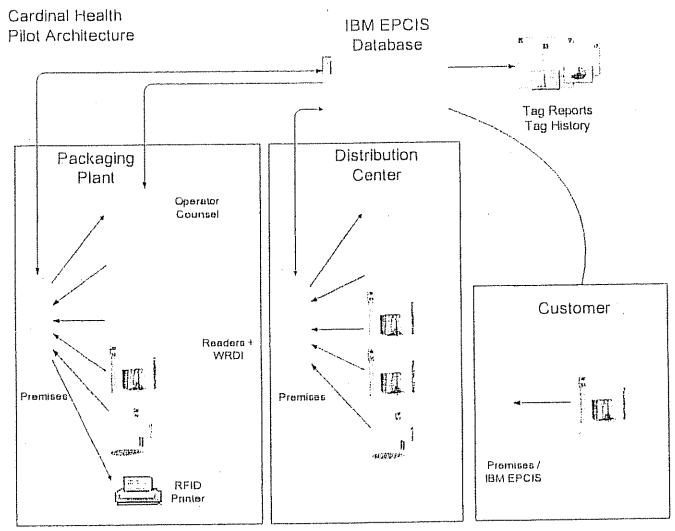
Architecture For Interoperability



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Definitions

- Aggregation: the collecting of individual units into a whole; a massing together or clustering of independent but similar units[1]
  - For example: 12 units = 1 case
    100 cases = 1 pallet
- Commission: the act of granting certain powers or authority to carry out a particular task or duty[2]
  - For example: RFID Tag is granted permission to carry data for a specific organization
- Inference: the act or process of deriving logical conclusions from premises known or assumed to be true; the act of reasoning from factual knowledge or evidence[3]
  - For example: If a case can be identified, contents are assumed to be known
- Interoperability: the ability to exchange and use information; the capability of being used or operated reciprocally[4]
  - For example: A manufacturer's system sends product information to a wholesaler in a generally accepted standard format

1. "aggregation." *Merriam-Webster's Dictionary of Law*. Merriam-Webster, Inc. 28 Nov. 2006 and *The American Heritage® Stedman's Medical Dictionary*. Copyright © 2002, 2001, 1995 by Houghton Mifflin Company. Published by Houghton Mifflin Company. (Dictionary.com)
2. "commission." *The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004. 28 Nov. 2006. (Dictionary.com)
3. "inference." *The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004. 28 Nov. 2006. (Dictionary.com)
4. "interoperability." *WordNet® 2.0*. Princeton University. 30 Nov. 2006 and "interoperability." *WordNet® 2.0*. Princeton University. 30 Nov. 2006 (Dictionary.com

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RFID Pilot Product Selection

- Non Major Pharma Company
- Product Diversity
  - Tablet Size/ Bottle Size
  - Unit Count
  - Round Bottle Vs Square
- Two Products
  - Rx A – Mid-tier manufacturer
    - Large tablet, 90 count unit, square bottle
    - Production run - 7/7/2006
  - Rx B - Mid-tier manufacturer
    - Small tablet, 90 count unit, round bottle
    - Production run - 7/20/2006

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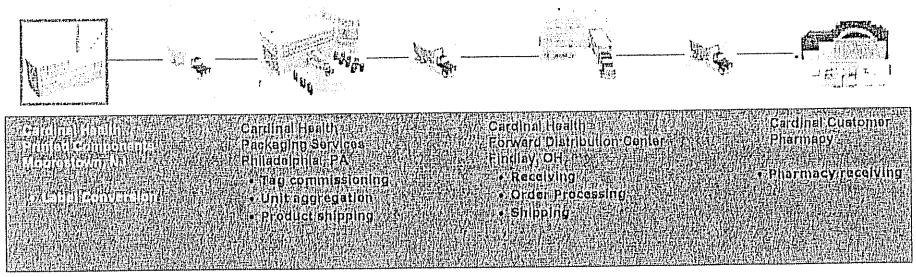
RFID Supply Chain Pilot

- Tagged product will flow through the following process:



- RFID Label Conversion
  - Print labels using existing label processes
    - Located at Cardinal printed component facility
    - Complete label printing and finishing capability
  - RFID tag insertion as a secondary operation

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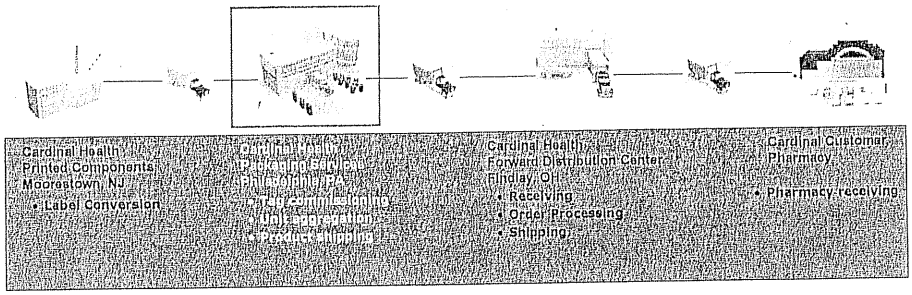
RFID Supply Chain Pilot

- Tagged product will flow through the following process:



- Product Packaging
  - Encoding in-line (read, write, read)
    - NDC & unique serial number is encoded
    - Production speed target – 120 bottles per minute
  - Aggregate units to cases simultaneously in production
  - Aggregate units to cases to pallets simultaneously - shrink wrap station
  - Read units and cases on outbound shipment

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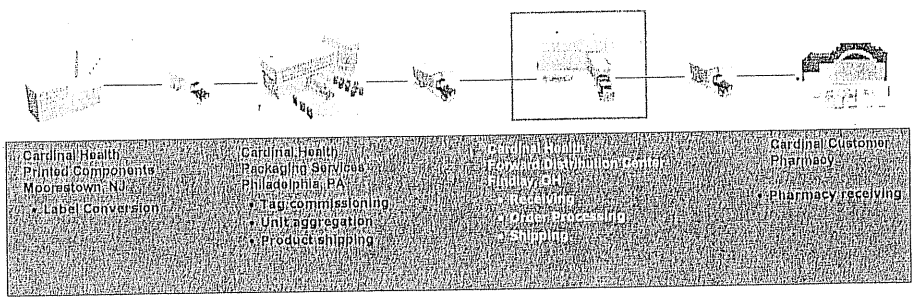
RFID Supply Chain Pilot

- Tagged product will flow through the following process:



- Distribution
  - Read cases and units on pallet at receiving
  - Read cases and units in singular format on conveyor
  - Read units in totes ready for shipment
  - Read units on cart with 30 totes on outbound shipment at shrink wrap
  - Read units on cart on outbound shipment

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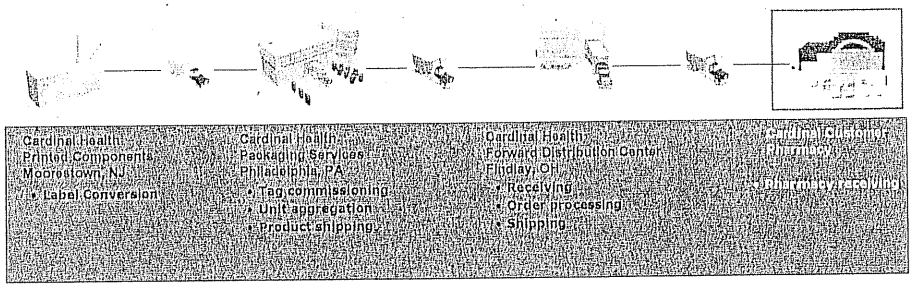
RFID Supply Chain Pilot

- Tagged product will flow through the following process:



- Pharmacy
  - Read units on inbound shipment (cart of 30 totes)

CardinalHealth

CardinalHealth

RFID Pilot Results

Overall Results

Location	Item Level Read Rates		Case Level Read Rates	
	Rx A	Rx B	Rx A	Rx B
Unit encoding yield during packaging	97.7%	94.8%	N/A	N/A
Unit to case aggregation	96.9%	99.7%	91.8%	100%
Case to pallet aggregation	56.4%	80.8%	100%	99.7%
Packaging shipping	9.2%	14.3%	82.3%	100%
Distribution Center pallet receiving	7.8%	9.5%	76.3%	100%
Distribution Center case receiving	92.1%	97.1%	99.4%	100%
Distribution Center customer QC	N/A	99.6%	N/A	
Distribution Center turntable	N/A	64.2%	N/A	
Distribution Center shipping	N/A	47.1%	N/A	
Customer receiving	N/A	88.2%	N/A	

Represents best opportunity for RFID tag reads

CardinalHealth

Read Rate Conclusions

- Overall
  - RFID tags can be successfully inlaid under existing FDA-approved pharmaceutical label stock
  - Packaging lines can be run at validated speeds while encoding and verifying RFID tag application
  - A single frequency (UHF) has the potential to work in critical points from pharmaceutical packaging to pharmacy receipt
  - No tag failures were encountered in any stage of the pilot

CardinalHealth

Read Rate Conclusions

- Units
  - Item-level reads are not possible when cases are stacked on a pallet
  - Unit read rates within mixed totes are highly reliable (>99%) but have not achieved six sigma quality

CardinalHealth

Read Rate Conclusions

- Cases
  - 100% read rates of case tags on a full pallet are potentially obtainable, but further testing is needed
  - Case read rates on a moving conveyor at shipping and receiving had read rates in excess of 99%

CardinalHealth

Overall Conclusions

- RFID technology is feasible for "Tracking & Tracing" item level drugs in the pharmaceutical supply chain provided the following conditions and processes are met:
  - Item level reads are limited to individual each and case read processes with conditions managed to an ideal / consistent state
  - Inference is allowed to become an acceptable practice in the normal distribution process schemes
  - Full interoperability of systems from manufacturer to pharmacy
  - Barcode technology is used in a redundant / complementary strategy to allow "Track & Trace" in areas of privacy concerns, biologic product distribution and RFID tag failure
  - Implementation is measured and managed in a manner consistent with the technology capability, the compliance risk and the financial impact on individual stakeholders
  - Higher levels of collaboration are initiated among stakeholders to identify opportunities in the supply chain to significantly improve efficiencies and reduce costs

CardinalHealth

Attachment 6

Comments to the Board of Pharmacy by the California Retailers' Association

CALIFORNIA RETAILERS ASSOCIATION
980 NINTH STREET, SUITE 2100 · SACRAMENTO, CA 95814
(916) 443-1975 · FAX (916) 441-4218

December 1, 2006

Ms. Virginia Herold
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

RE: Timeline of Community Pharmacy Implementation of Electronic Pedigree Requirement in California

Dear Ms. Herold:

The California Retailers Association (CRA) is writing on behalf of our members in response to the Board of Pharmacy Enforcement Committee's solicitation of a timeline regarding chain pharmacy implementation of electronic pedigree.

Upon inquiry to CRA's chain drug store members, all of our members stress the need for retailers to engage in ongoing active involvement with the upstream drug supply chain components as they are developing and implementing the technology to support electronic pedigrees for prescription drugs.

As you know, community pharmacies are the last link in the drug supply chain. Under the statute, manufacturers will be generating the electronic pedigrees and passing them to wholesalers. Wholesalers will then pass the electronic pedigrees to retail pharmacies. CRA's members are concerned that pharmacies must be given an adequate amount of time to implement electronic pedigree once manufacturers and wholesalers have implemented interoperable e-pedigree technology. Once the interoperable e-pedigree technology is developed and adopted by others in the supply chain, pharmacies will need an opportunity to implement the technology themselves.

Once interoperable technology is integrated by the rest of the drug supply chain and made available to community pharmacies, retailers can begin to pilot and validate these electronic pedigree systems. As components of implementation, pharmacies will need to test the e-pedigree system intra-pharmacy, monitoring the viability, validity, and protection of patient privacy for the passage of electronic pedigree between each pharmacy and each of its wholesalers and/or manufacturers. To avoid patient delays in receiving prescription medications, pharmacies will also need to ensure that the e-pedigree systems work in "real-time" so as not to affect efficiency in pharmacies or productivity in pharmacy distribution centers. This process, from the time interoperable

technology is developed through the phases of testing, validation and deployment across all pharmacies in California, could take as long as two years.

For each manufacturer, pharmacies will have to develop methods for storing and accessing electronic pedigrees. Given the number of manufacturers (both brand and generic) and prescription pharmaceutical products, it is believed that such a database will rapidly evolve into an extremely large database, challenging any current software capabilities in place in pharmacies today. Our members repeatedly express concerns about other capacity issues. The concern is not merely focused on the viability of software, hardware and electronic pedigree readers, but also on personnel constraints. Pharmacies are anxious about the number of individuals who will possess the necessary skills to install the required equipment and launch the required software programs that will allow for the compatibility of electronic pedigree technology with chain pharmacy inventory systems. Companies cannot begin to train and/or recruit the appropriate personnel until manufacturers and wholesalers determine, develop, and fully integrate the technologies that will be used to implement electronic pedigree in the drug supply chain.

The community pharmacy industry consists of companies of varying sizes and technical capabilities. Companies have disparate levels of financial, technical and human resources. Community pharmacies with higher levels of automation and greater Information Technology support resources generally believe that they will be able to implement electronic pedigrees at the distribution level within approximately one year after full implementation of manufacturers and wholesalers. For the community pharmacies with lower levels of automation and relatively lower resources in general, there is a fear that the challenges of e-pedigree implementation may take them up to two years to complete testing and training and to integrate the necessary processes and technologies.

CRA's members are hopeful that manufacturers and wholesalers are able to fully implement electronic pedigree prior to January 1, 2009. For the reasons outlined above, community pharmacies will be unable to implement electronic pedigrees by January 1, 2009 if the others in the supply chain do not fully implement interoperable e-pedigree systems in a timeframe that allows pharmacies, as the last link in the drug supply chain, adequate opportunity to implement the technologies. As we push forward to an e-pedigree solution, we ask that the Board of Pharmacy be mindful of community pharmacies' need for adequate time to ensure viability, validity, patient privacy, and efficiency prior to the full implementation of electronic pedigree across the pharmacy industry. We look forward to actively working with the Board of Pharmacy and our partners in the drug supply chain to implement electronic pedigrees in a responsible and timely manner.

Sincerely,

Heidi Barsuglia
Director, Government Affairs

Attachment A

Meeting Summary of the Enforcement Committee and the Work Group on E-Pedigree December 12, 2006

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee and Workgroup on E-Pedigree

Meeting Summary of the December 12, 2006 Meeting

Radisson Hotel Sacramento
500 Leisure Lane
Sacramento, CA 95815

Present: Bill Powers, Board President and Chair
Ruth Conroy, PharmD, Board Member
Stan Goldenberg, RPh, Board Member
Rob Swart, PharmD, Board Member

Staff: Virginia Herold, Interim Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Karen Cates, Acting Assistant Executive Officer
Anne Sodergren, Legislative Coordinator
Joshua Room, Deputy Attorney General
Spencer Walker, Staff Counsel

Call to Order:

Chairperson Powers called the meeting to order at 9:33 a.m.

Letter to the DEA Supporting the Ability of Prescribers to Issue Multiple Prescriptions for Schedule II Controlled Drugs at One Time

Chairperson Powers referred the committee to a copy of the board's letter to the DEA supporting a proposed shift in DEA policy to allow prescribers to write multiple prescriptions (up to a 90-day supply) for Schedule II controlled substances during a single office visit. For example, this revision in DEA policy would allow prescribers to provide patients with three 30-day prescriptions at once, writing "do not fill until" a specified date on the additional prescriptions eliminating the need for patients to return to visit the prescriber simply to obtain a new prescription.

Proposal to Develop a Ethics Course For Pharmacists, Modeled After the Experiences of the Medical Board of California in Establishing an Ethics Course for Physicians

Lorie Rice, Associate Dean, External Relations, UCSF School of Pharmacy, and former public member of the Medical Board of California, provided a presentation on her experiences in developing an ethics course for physicians who had been disciplined by that board. This course was developed following the Medical Board's determination that existing ethics courses available for physicians were inadequate for the frequent ethical violations that come before the board for discipline.

Existing ethics courses, when found, focus on the theory behind ethics, similar to what one learns in traffic school. The Medical Board thought that such courses lacked the opportunity for the individual to think about the ethical violation and its impact on the individual, the patient and society. Of 770 physicians disciplined by the Medical Board, 75 percent were ethics violations in part.

Ms. Rice stated that there are two major types of violations: (1) quality of care issues, e.g., where a prescription order has been misinterpreted, dispensed incorrectly, or a patient has been inappropriately consulted, and (2) personal conduct issues, e.g., diversion for self use, sexual misconduct, adulteration of drugs.

If the board were to develop a course, there are some issues the board would need to address:

(1) Who would be part of the task force to develop the components?
(2) What type of cases would be referred?
(3) What criteria would be needed to assess rehabilitation, redemption and contrition? Is there a willingness to change on the part of the licensee?
(4) How to build skills involving empathy, to ensure there is an opportunity to focus about the impact of the licensee's action on society and how it impacted patients?
(5) Follow up for each licensee is needed in 6 –12 months

The Medical Board course is set up for a maximum of 12 individuals, and she indicated it would seem feasible to have physicians and pharmacists in the same class. According to the Medical Board regulations, the class must be at least 22 hours.

The timeline for the Medical Board to develop its course was:

- 2002: Formation of the Task Force
- 2003: Public Comment periods
- 2004: Regulation Hearing
- 2005: Regulation became effective

Ms. Rice referred to the Medical Board's regulation which was provided in the meeting materials. She stated that as the former executive officer of the Board of Pharmacy,

she has some knowledge about pharmacy violations and would be willing to assist the board in developing the course if the board decides to develop a course.

Chairperson Powers invited Ms. Rice to attend the January 2007 Board Meeting to determine the board's interest in proceeding with this project at this time.

Presentation by the FDA on the Implementation of the Prescription Drug Marketing Act Provisions Involving Pedigrees

Ilisa Bernstein, Director of Pharmacy Affairs, Office of the Commissioner, US Food and Drug Administration, joined the meeting via telephone from Washington, DC. Ms. Bernstein stated that very recently a US district court judge in the eastern district of New York issued a written order granting a preliminary injunction preventing the FDA from implementing the paper pedigree requirements which had been set to go into effect in December 2006, exempting authorized distributors. She stated that because the FDA is involved in litigation regarding the PDMA pedigree requirements, there is nothing that she could state at this time until the FDA releases a policy statement.

However, she complimented the efforts and leadership role that California has taken in moving forward an electronic pedigree system to further secure the drug supply.

Workgroup on E-Pedigree

Progress of the EPCglobal Workgroup

1. Presentation by EPCglobal:

Robert Celeste, EPCglobal, and Ron Bone, McKesson Corporation, provided a PowerPoint presentation on the development of standards for electronic pedigrees (**Attachment 1** contains this presentation).

EPCglobal is currently at the final stages of review for intellectual property rights. This is the final stage of review before the standards will be finalized. Completion of this review is expected in early January 2007.

EPCglobal reported the following progress:

- Pedigree management use cases: objective: define all supply chain use cases, processes and information needs for use in creating pedigree messaging standards.
  Status: complete
- Pedigree messaging standards: objective: define a standard format for the pedigree messaging standard that meets all federal and state requirements.
  Status: all standards work completed, prototype event was successful, technical review passed, intellectual property review underway
- Item level tagging: objective: define requirements for tagging pharmaceuticals at the item level; this includes requirements for

manufacturing lines, distribution environments, transportation and retail environments.
Status: requirements complete. A high frequency technical work was formed to define the standard. High frequency and ultra high frequency pilots are underway to provide uniform air interface protocol at the item level. The high frequency standard is expected to completed in the 3rd quarter of 2007

- Serialization: objective: define requirements to be encoded on the electronic tag.
  Status: requirements completed. Two identifiers were identified for use (global trade item number (GTIN) and serialized shipping container number (SSCC)). All remaining issues will be addressed by the newly formed serialization group.
- Decommissioning: objective: define requirements for decommissioning tags as they leave the supply chain.
  Status: work to begin in January 2007, timeline is 6 months
- Track and trace: objective: define supply chain use cases, processes and information needs for sharing EPC-related data for forward and reverse logistics.
  Status: forward and reverse logistics processes and data exchanges completed, additional use cases to be addressed for 3rd party logistics and repackagers, product recall, data sharing strategy and guidelines are being developed.

Mr. Bone stated that the features of the pedigree standard will support: item level serialization, electronic signatures, RFID using non-line of sight identification of pallets, cases or items, and inference.

EPCglobal's next steps will be to work through scenarios with the Board of Pharmacy, host a workshop for regulators from states with electronic pedigrees, and work with the formed industry adoption workgroup on serialization and time tagging issues. There will also be a regional summit for hospital issues on February 20.

Some of the issues that will be addressed by EPCglobal in the coming weeks will also involve use of NDC numbers involving controlled substances, which may be an issue when controlled substances are being transported.

The generic manufacturers are also interested in joining some of the pilot studies.

Board Member Goldenberg thanked the Mr. Bone and Mr. Celeste for the presentation, and acknowledged and commended those who have worked so hard to get to current status that was highlighted in EPCglobal's report. He also reaffirmed the board's position that 2009 is the implementation date for implementation of electronic pedigree requirements in California.

2. Presentations by Manufacturers, Wholesalers and Pharmacies on Implementation of Electronic Pedigrees:

(a) AmerisourceBergen Corporation:
Shay Reid, Vice President, Integrated Solutions, AmerisourceBergen (ABC), provided a PowerPoint presentation describing a pilot project initiated using electronic pedigrees with IBM (**Attachment 2** contains this presentation) that would track all drug products from manufacturers, through wholesalers and repackagers to pharmacies. Mr. Reid stated that ABC initiated this project in the belief that it has an opportunity to either be a leader or follower with respect to electronic tracking of drug products.

Mr. Reid walked through various scenarios involving a document-based pedigree that would be passed from one owner to the next as a drug product moves through the distribution channel. He noted that problems include massive redundant data repositories, especially for those near the end of the distribution channel. There is little other use that a company will gain from such repositories, except for compliance with requirements.

He then highlighted the "track and trace" model that is being tested by ABC and IBM. This system passes only a minimal amount of data as the product moves through the distribution channel, but that at any point, full data describing all items and all ownership can be quickly accessed and obtained by legitimate users. The system can also be accessed to obtain real time receiving and shipping information and for better management of inventory.

The ABC pilot will use ultra high frequency, 2-D bar codes and new high frequency tags on the drug products tested.

Mr. Shay indicated that inference will be one component evaluated as products are shipped from manufacturer to wholesaler. He also indicated that inference will be evaluated on mixed totes of products from wholesalers to pharmacies. Board staff indicated that these practices will be carefully reviewed for compliance with California requirements as the data is collected during the pilot.

Progress reports will be made to the board at future Workgroup on E-Pedigree meetings.

(b) Cardinal Health
Julie Kuhn, Cardinal Health, presented information on a RIFD pilot run on ultra high frequency tagging of drug products from manufacturers through the supply chain (**Attachment 3**).

The results of this study indicate that it is feasible for these tags to be added to product containers and be read throughout the system – under this pilot, they were read 95 to 97 percent of the time. Cardinal Health believes after some adjustment, readings near 100 percent can be accomplished, without disruption to the distribution channel.

Two different types of containers were tested, a round container and a square container. Tagging at various places (container, pallet, etc.) was also tested.

The results indicate:

- RFID tags can be successfully inlaid under existing FDA-approved pharmaceutical label stock.
- Packaging lines can be run at validated speeds while encoding and verifying RFID tag application.
- A single frequency (UHF) has the potential to work in critical points from pharmaceutical packaging to pharmacy receipt.
- No tag failures were encountered in any stage of the pilot.
- Item-level reads are not possible when cases are stacked on a pallet
- Unit read rates within mixed totes exceed 99 percent, but are not at 100 percent.
- 100 percent read rates at the case level on pallets are potentially obtainable
- Case read rates on a moving conveyor at shipping and receiving had read rates exceeding 99 percent.

The conclusion of the study was that RFID technology is feasible for tracking and tracing item level drugs in the pharmaceutical chain provided that higher levels of collaboration are initiated among stakeholders to identify opportunities in the supply chain to improve efficiencies and reduce costs.

Ms. Kuhn indicated that there has been more collaboration within the last six months among industry partners than in the last 18 months. She also commented that generation 2 UHF tags are superior in quality to the Gen 1 tags.

3. Presentation on Technology for Electronic Tagging of Items

Bertrand Teplixky, Secure Packaging Systems, provided a demonstration of a form of electronic tagging that would be positioned in the cap of a medicine container. Mr. Teplixky indicated that such tags could be beneficial for high cost biologicals and are in use in Europe. They are also capable of being developed with Braille markers and with color-coded caps.

During discussion mention was made about testing of biological products for stability following 48 hours of exposure to high frequency fields without any change in the medication inside the containers.

4. Comments by the California Retailers Association

Heidi Barsuglia, Director, Government Affairs, California Retailers Association, provided comments from the chain store pharmacies in California. She discussed comments provided in a letter dated December 1, 2006.

The CRA's members are concerned that the 2009 date for implementation of electronic pedigrees in California will be impossible for the state's chain-store pharmacies because they are at the end of the distribution channel, and the technology put in place by manufacturers and wholesalers will need to be readable, adopted and installed in pharmacies before pharmacies can comply with the requirements.

Ms. Barsuglia indicated that pharmacies need to initiate testing to ensure these systems are operable, can protect patient privacy and will not delay the dispensing of medication to patients. She indicated that this process may take at least two years.

Moreover, pharmacies are concerned that they will need to develop methods for storing and accessing electronic pedigrees, and these databases will be huge databases at the store level to manage and maintain. There are also concerns about whether there will be adequate staff available to install these systems and provide training to pharmacy staff about how to use them. These latter tasks cannot be initiated or planned for until the manufacturers and wholesalers fully implement and integrate the systems for electronic pedigrees that will be passed to the pharmacies.

She concluded that the pharmacies will need time beyond 2009 to be able to implement the standards.

2007 Meeting Dates

The committee announced the following Enforcement Committee and E-Pedigree Workgroup Meetings for 2007:

- March 21
- June 20
- September 20
- December 5

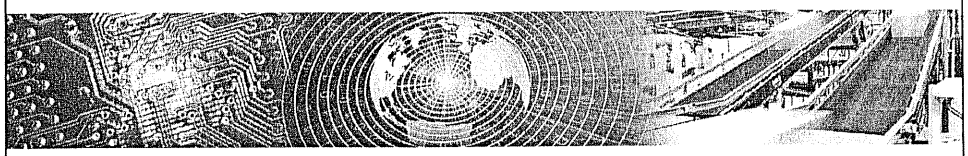
At the current time all these meetings are planned to be held in Sacramento.

Adjournment

There be no additional business, Chairperson Powers adjourned the meeting at 12:30 p.m.

Attachment 1

Presentation by EPCglobal
December 12, 2006



California Board of Pharmacy

State of Pedigree and EPC/RFID Standards

December 12, 2006

GS1 EPCglobal

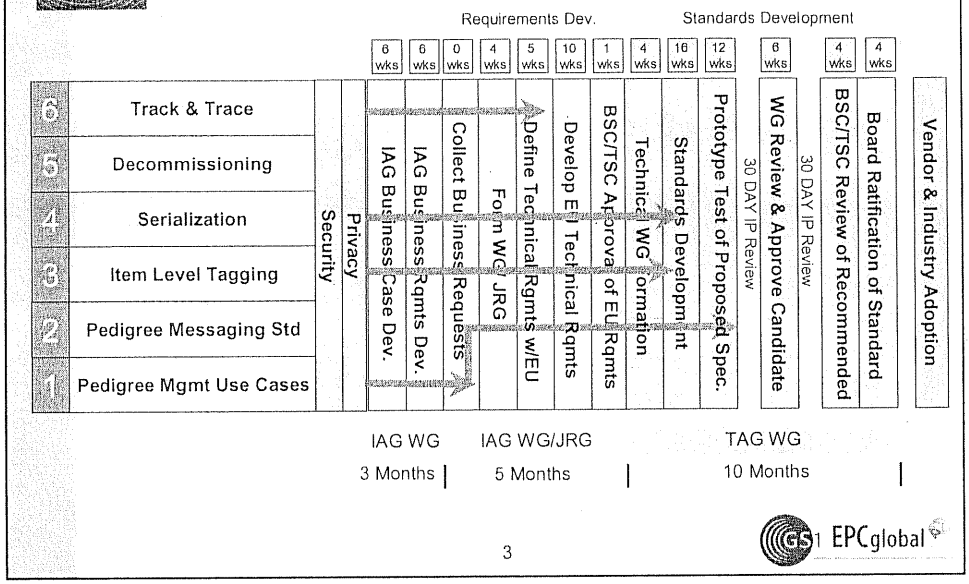
Agenda

- Standards Progress
- Pedigree Review Event

GS1 EPCglobal

Standards Update

Last Report

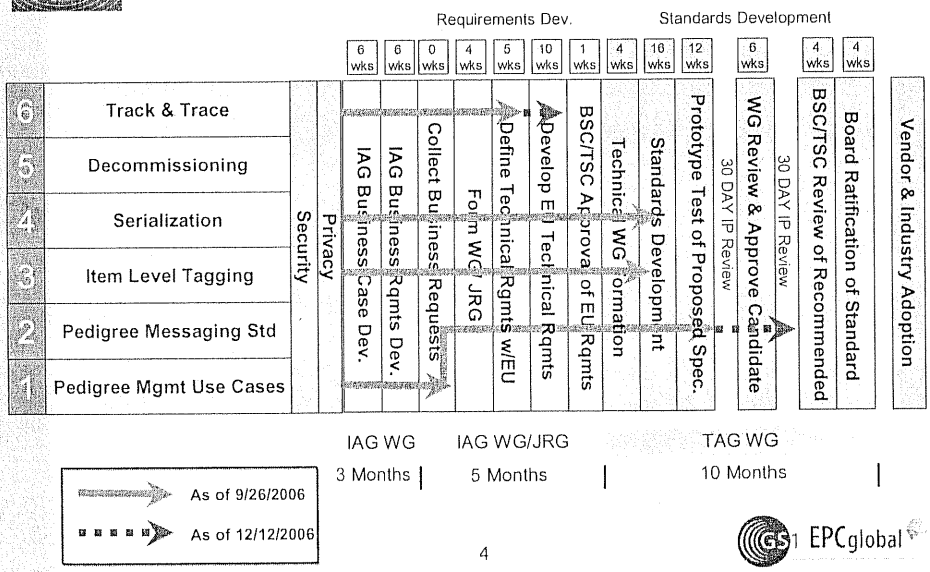


GS1 EPCglobal

3

Standards Update

Last Report



GS1 EPCglobal

4

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define all supply chain use cases, processes and information needs for use in creating a Pedigree Messaging Standard.

Status: Complete

5

GS1 EPCglobal

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- All Standards work complete (Certification Requirements due 12/20/2006).
- Prototype event was successful.
- Passed Technical Review
- Intellectual Property Review period started
- **Ratification of standard anticipated 4Q/2006.**

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

Status:

- Requirements complete. Resulted in a High Frequency technical working group to define the standard.
- HF & UHF initiatives underway to provide uniform air interface protocol at item level.
- HF Standard expected 3Q07.

GS1 EPCglobal

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define requirements the EPC identifier to be encoded on an RFID tag.

Status:

- Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Joint group formed between EPCglobal Healthcare and Life Sciences Business Action Group (HLS) and GS1 Healthcare User Group (HUG).
- All remaining issues to be addressed by new Serialization group.

GS1 EPCglobal

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define requirements and/or guidelines for decommissioning tags as they leave the supply chain.

Status:

- HLS Work Group to be chartered & initiated January 2007
- Anticipate six month effort
- DEA interest in this capability is extremely high
- Solutions expected to span a mix of hardware, software and process responses
- Potential for this work to expand cross-industry

GS1 EPCglobal

Standards Update

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges have been completed
- Common vocabularies and location identifiers have been drafted
- Additional use cases to be addressed include:
  - 3rd Party Logistics Providers & Repackers
  - Product Recall
- Data Sharing Strategy & Guidelines are currently being addressed

GS1 EPCglobal

Pedigree Messaging Standard

Expected Ratification by end of 2006

GS1 EPCglobal

Review of Pedigree Standard
Features Supported

Feature	Required?	Support?
Item level serialization - Unique identification of each and every bottle of medication	No	Yes
Electronic Signatures - Ensures identity of Pedigree issuing company	Yes	Yes
RFID - Non Line of sight identification of Pallets, Cases or Items	No	Yes
Inference - Upon visual inspection, assuming content of containers (Pallets, Cases, Totes) based on Pedigree or Advanced Ship Notice (ASN)	No	Yes
Manufacturer initiated Pedigree - Manufacturer sends first pedigree to next participant in supply chain (as opposed to the first distributor)	No	Yes

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GS1 EPCglobal

Next Steps

- Walk Board of Pharmacy through Pedigree scenarios
- Host workshop for Regulators from States with electronic pedigree bills
- Industry Adoption WG formed
  - Working with Industry Associations on Serialization & Item Level Tagging issues
- Upcoming events:
  - EPCglobal Inc Joint Action Group Event (Jan 8-12, 2007)
  - Ongoing work on
    - Serialization
    - Item Level Tagging
    - Track and Trace
- Provide regular status updates to CA BoP

GS1 EPCglobal

Pedigree Review Event
Agenda

- Structure of the Pedigree Standard
- Implementation Guidelines Review
- Walkthrough seven Pedigree scenarios
- Pedigree Software Certification Process
- Pedigree Standard Revision Process

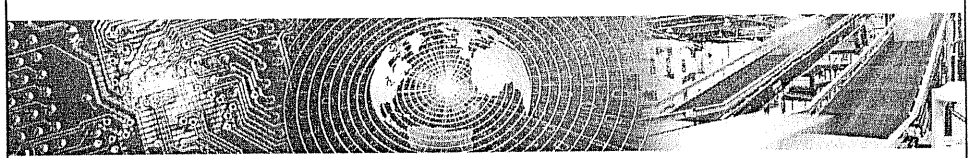
GS1 EPCglobal

Planned Activities
Regional Hospital Summits

Date	City	Event
January 23rd	Dallas	
February 20th	California	
March 1st	New Orleans	Healthcare Information and Management Systems Society (HIMSS)
March 13th	Boston	
April 17th	Chicago	
May 10th	Washington D.C.	American Hospital Association (AHA)

15

GS1 EPCglobal



Questions?

GS1 EPCglobal

Additional Slides

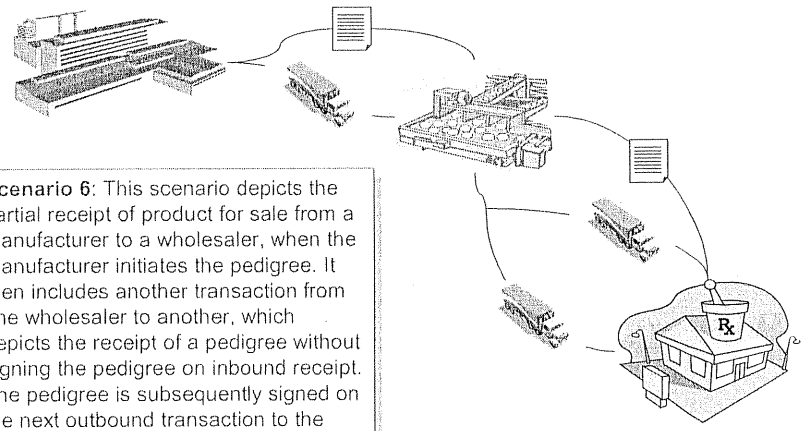
GS1 EPCglobal

EPCglobal Pedigree Prototype Event
Scenarios

- **Scenario 1**: This scenario depicts the pedigree flow for the sale of a serialized product from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler then sells and ships one of the product items to a pharmacy DC.
- **Scenario 2**: This scenario depicts the sale of a non-serialized product from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 3**: This scenario depicts the sale from a wholesaler to a retail pharmacy DC, when a paper pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 4**: The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. The repack pedigree contains the pedigree for the source product used to create the repack products
- **Scenario 5**: This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.
- **Scenario 6**: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.
- **Scenario 7**: This scenario depicts the pedigree flow for the sale of a non-serialized product from a manufacturer to a wholesaler, when the wholesaler initiates the pedigree. The wholesaler then sells and ships the product to a pharmacy DC, then the pharmacy DC returns the product to the wholesaler. Then the wholesaler sells and ships the product to another pharmacy DC. This pharmacy DC also returns the product to the wholesaler.

EPCglobal Pedigree Prototype Event

Sample Scenario



Scenario 6: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.

GS1 EPCglobal

Attachment 2

Presentation by Amerisource Bergen, December 12, 2006

AmerisourceBergen

California Board of Pharmacy Update

Dec. 12, 2006

Shay Reid
Vice President, Integrated Solutions

- Primary Business:
  - Service both pharmaceutical manufacturers and healthcare providers in the pharmaceutical supply channel.
  - Provide pharmaceutical distribution and related services designed to reduce cost and improve patient outcomes.
  - More than 40 distribution centers throughout the US and other international locations.
  - 100% of ~11,500 Rx Products are Purchased Directly from One of 400 Different Manufacturers.

- California Presence
  - Three (3) state of the art distribution centers
  - Approximately 800 employees
  - Deliver to more than 3,000 California

AmerisourceBergen

California's Call to A New Frontier on March 16, 2006:

> *"We stand today on the edge of a new frontier,...a frontier of unknown opportunities and paths, a frontier of unfulfilled hopes and threats.... The new frontier...is not a set of promises, it is a set of challenges. It sums up not what I intend to offer the American people, but what I intend to ask of them."*
>
> John F. Kennedy – 1960 Presidential Campaign

California Asked the Pharmaceutical Industry For:

"Innovation to create a vision using available technology."

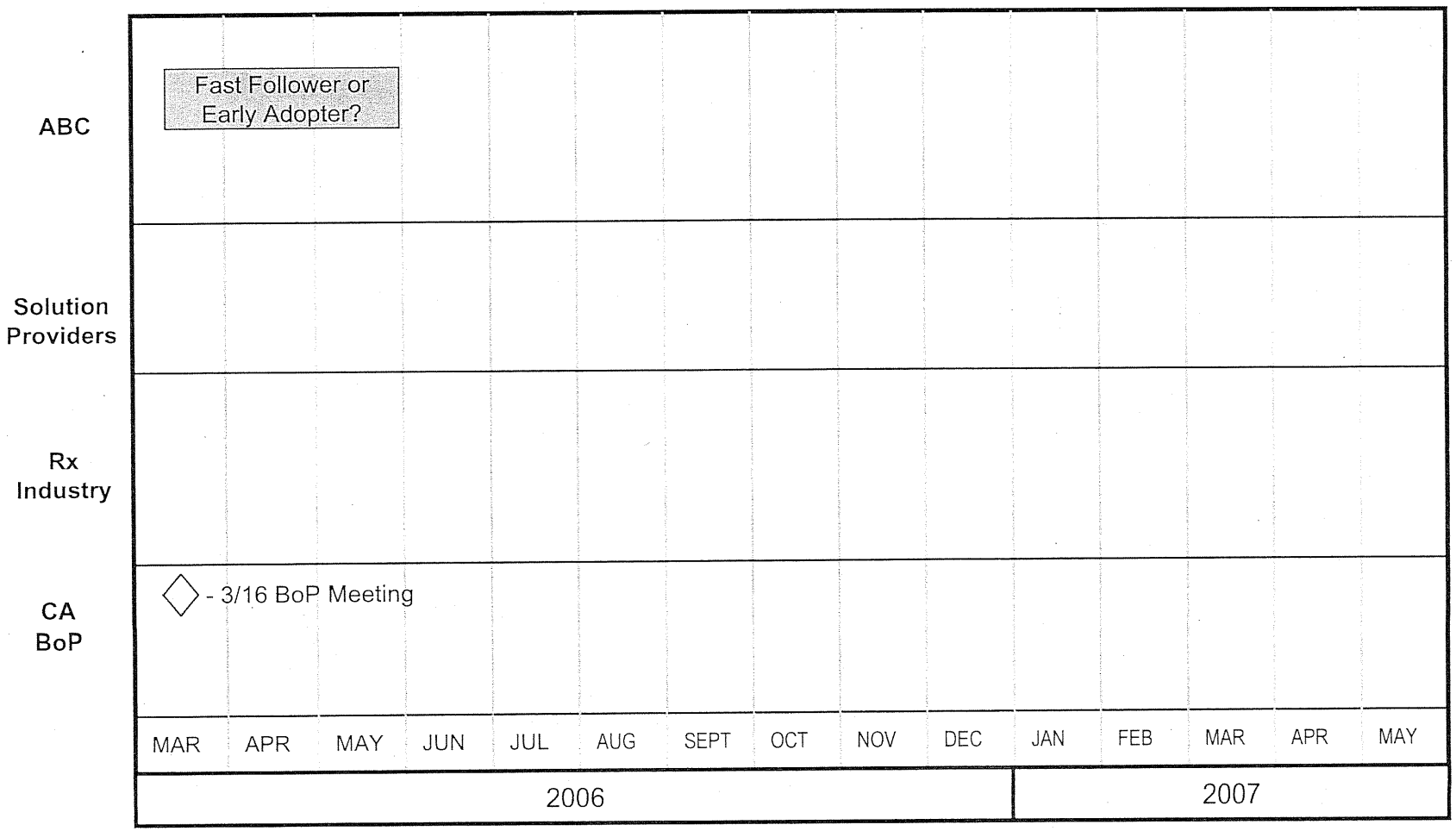
"Pioneers that can pave the way for others."

"Collaboration focused on patient safety."

"A milestone plan for adoption."

AmerisourceBergen

ABC's Decision:



AmerisourceBergen

ABC Choice – Fast Follower or Early Adopter?

FAST FOLLOWER	EARLY ADOPTER
Wait for Answers	Develop a Vision
Standards Victim	Collaboration
Project Team	Cross Functional Task Force
Investment in Solution	Investment in Future
Compressed Project Schedule	Design – Build – Evaluate Cycle

ABC Decided To Answer California's Call for Early Adopters to:

- Innovate
- Pioneer
- Collaborate
- Plan

Toward a Focus of Greater Patient Safety

- Right Product
- Right Time
- Right Place
- Right Quantity
- Reasonable Cost

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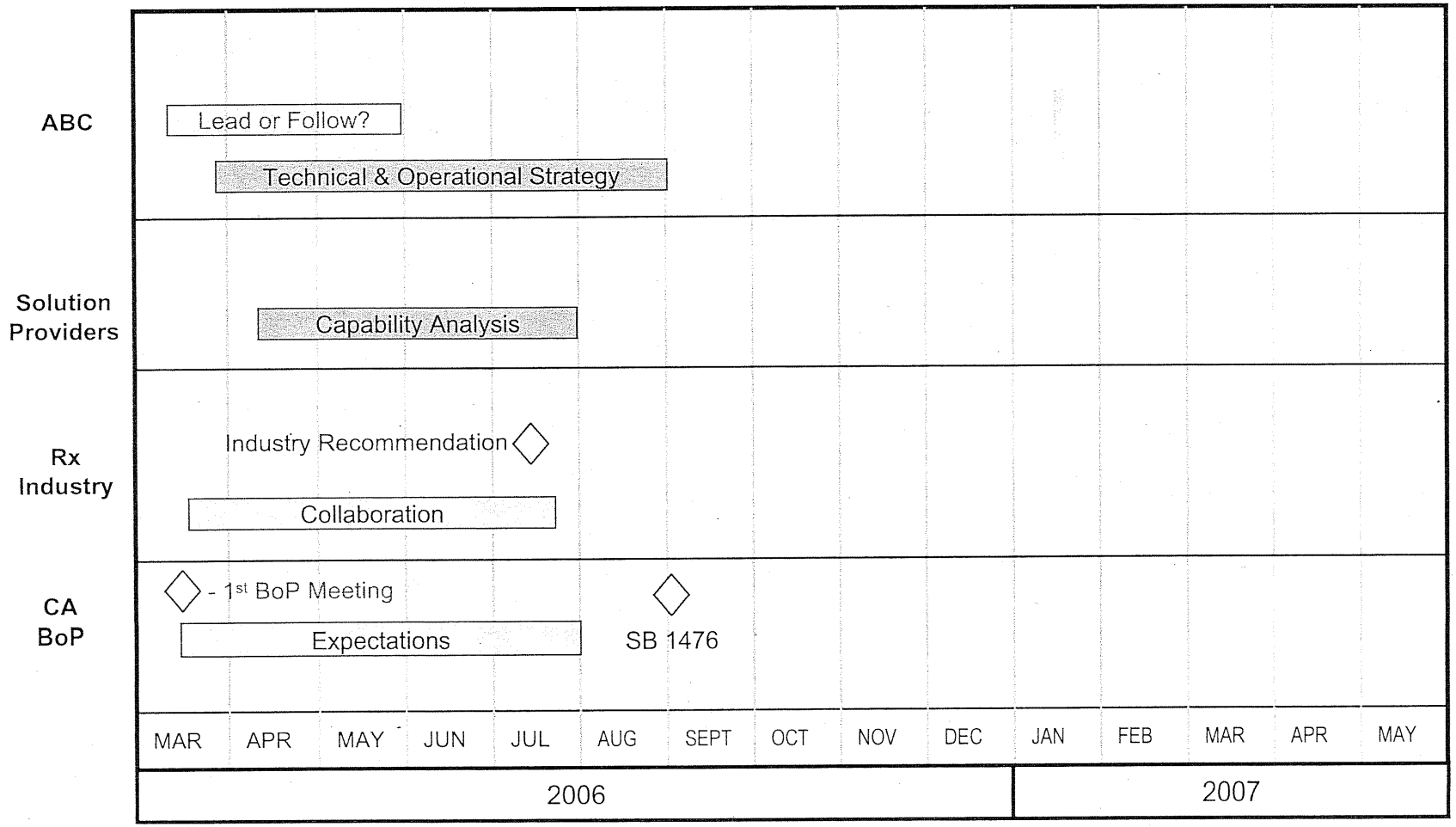
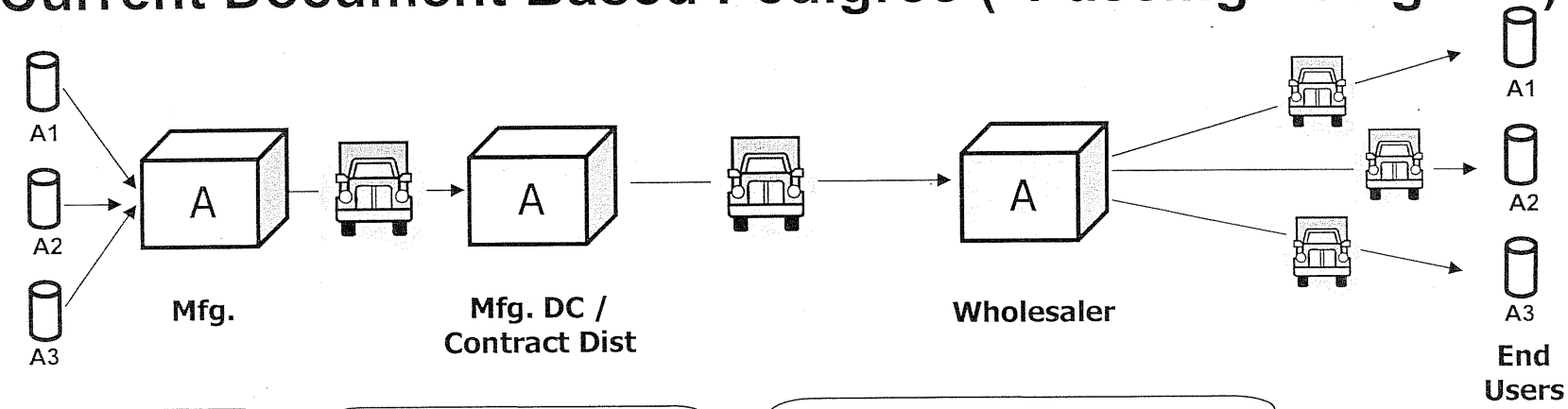
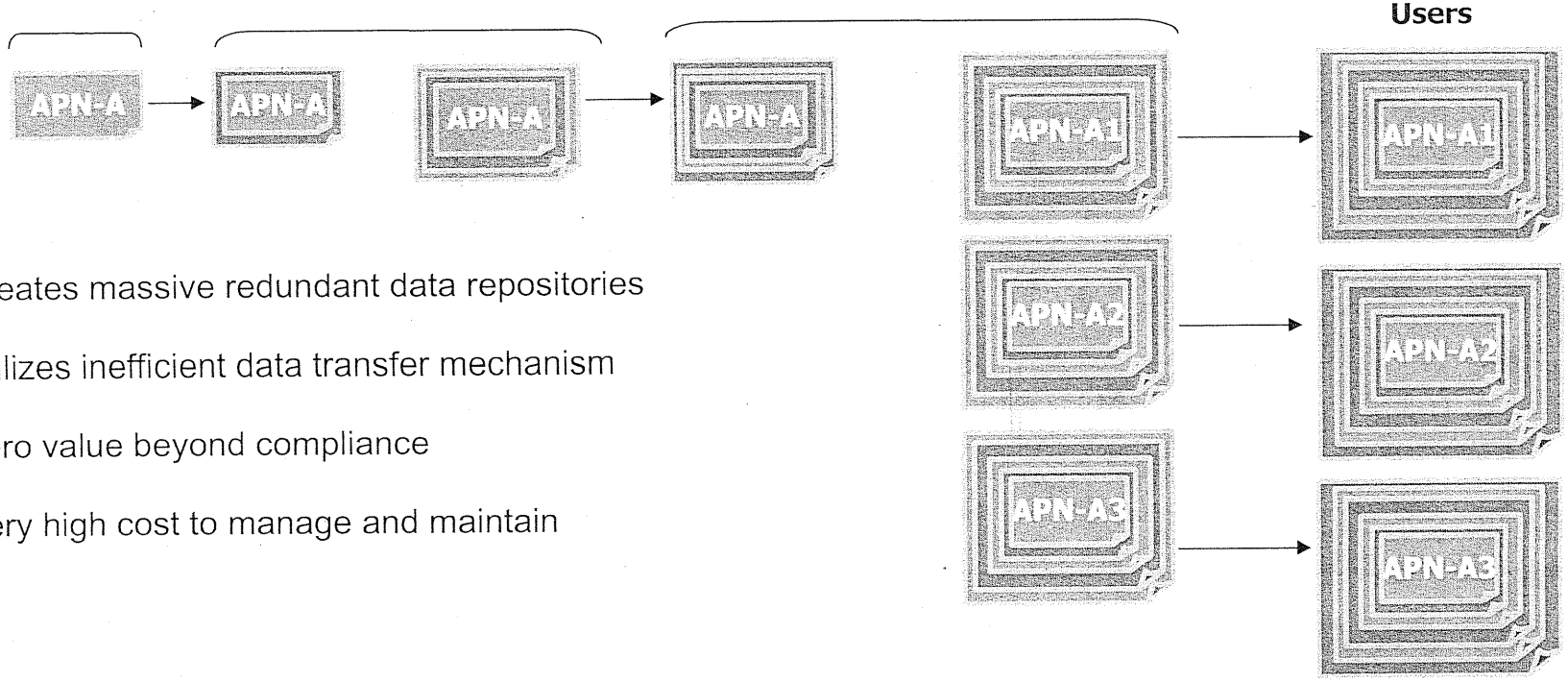
ABC's Plan to Innovate:



Current Document Based Pedigree ("Passing Pedigree"):





- Creates massive redundant data repositories
- Utilizes inefficient data transfer mechanism
- Zero value beyond compliance
- Very high cost to manage and maintain

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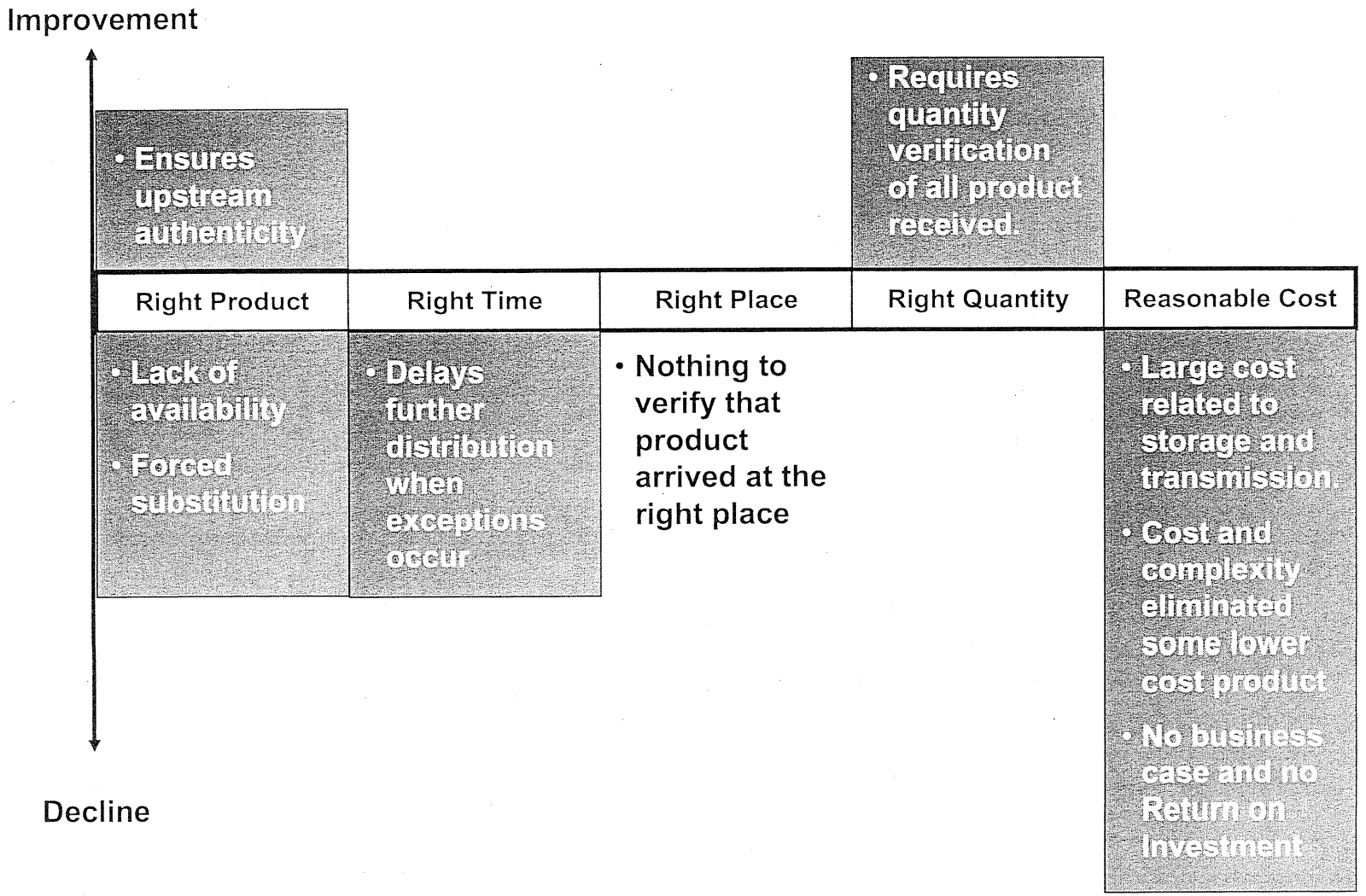
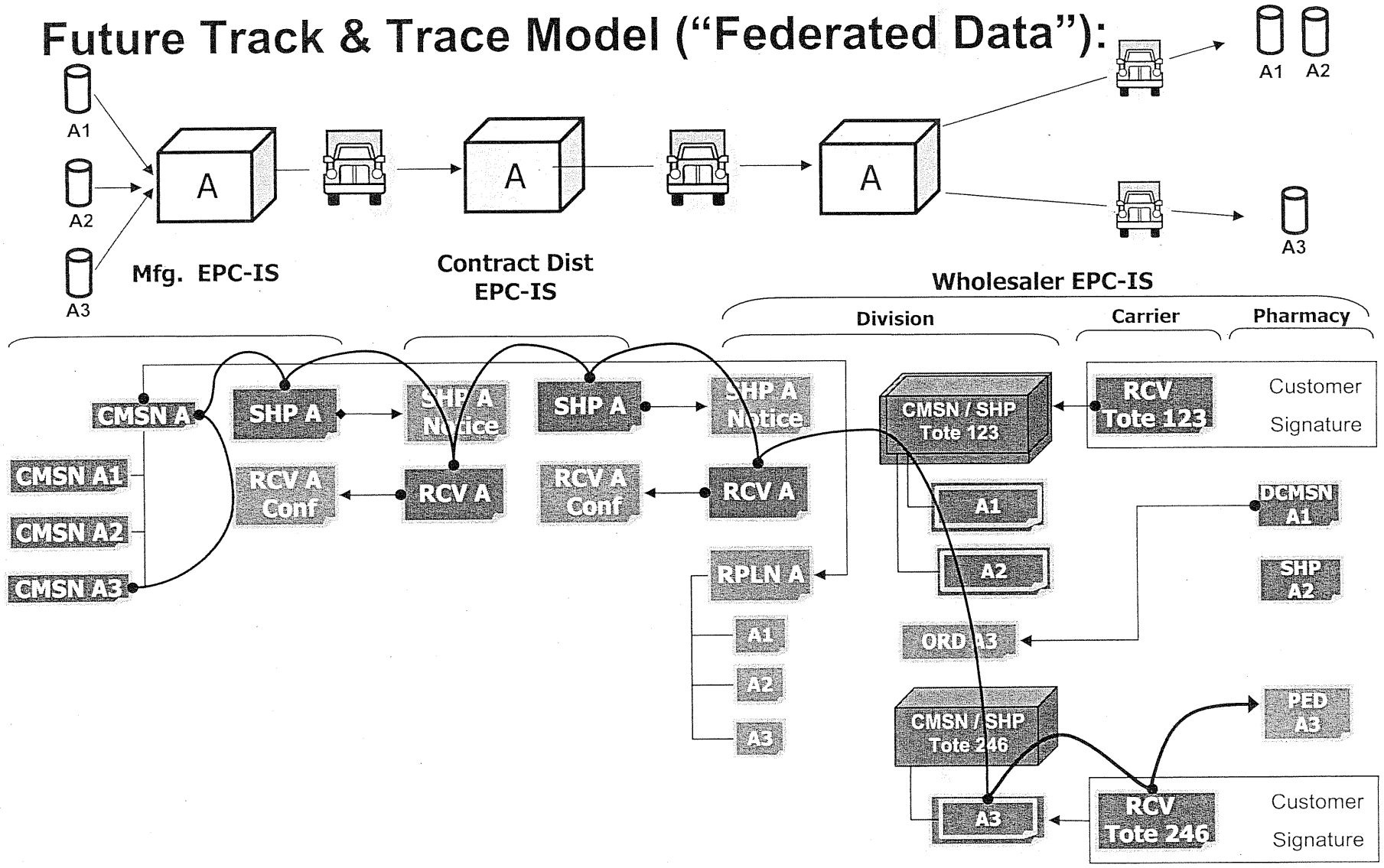
Current "Passing Pedigree" – Patient Safety Test:



Future Track & Trace Model ("Federated Data"):



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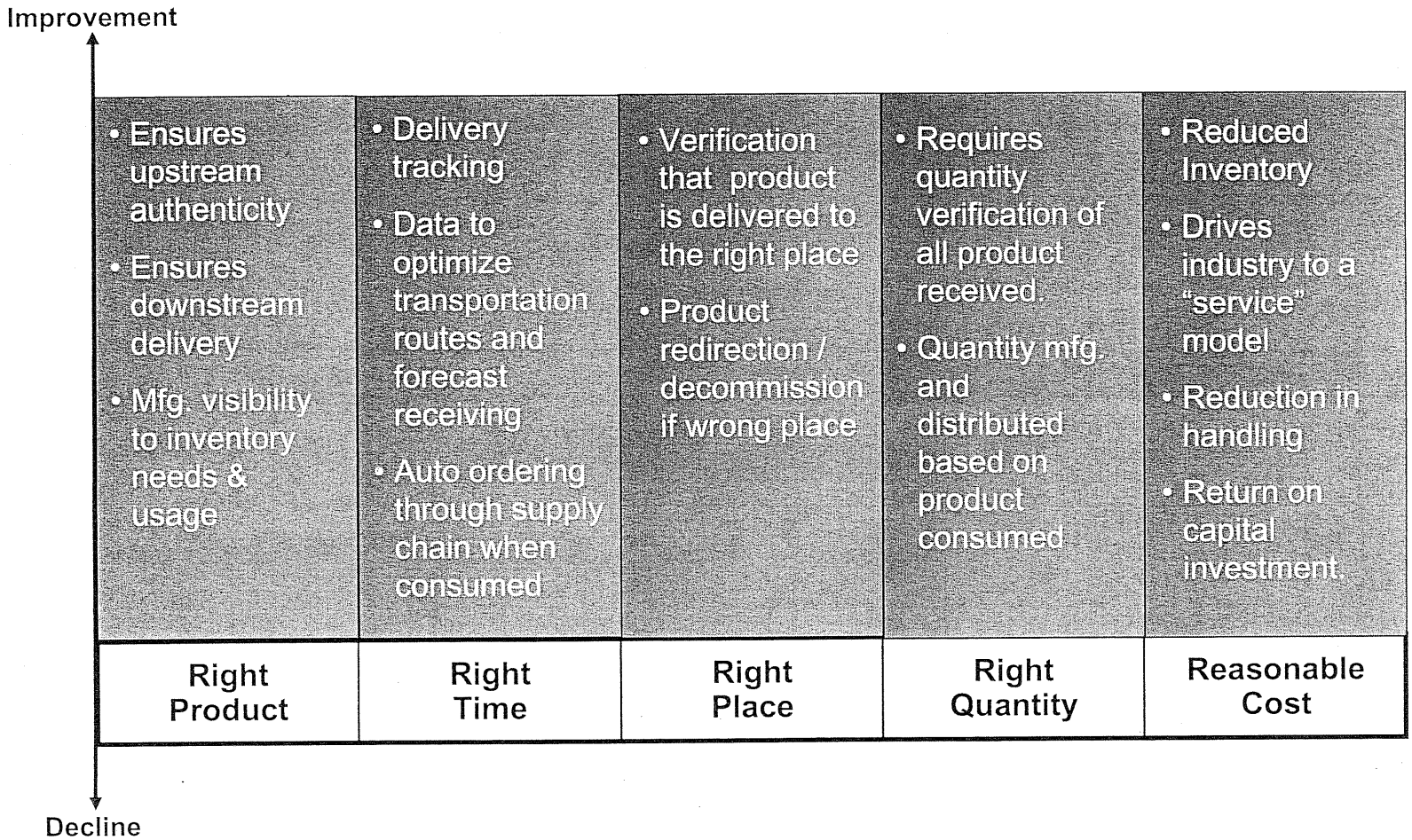
Future Track & Trace Model – Patient Safety Test:



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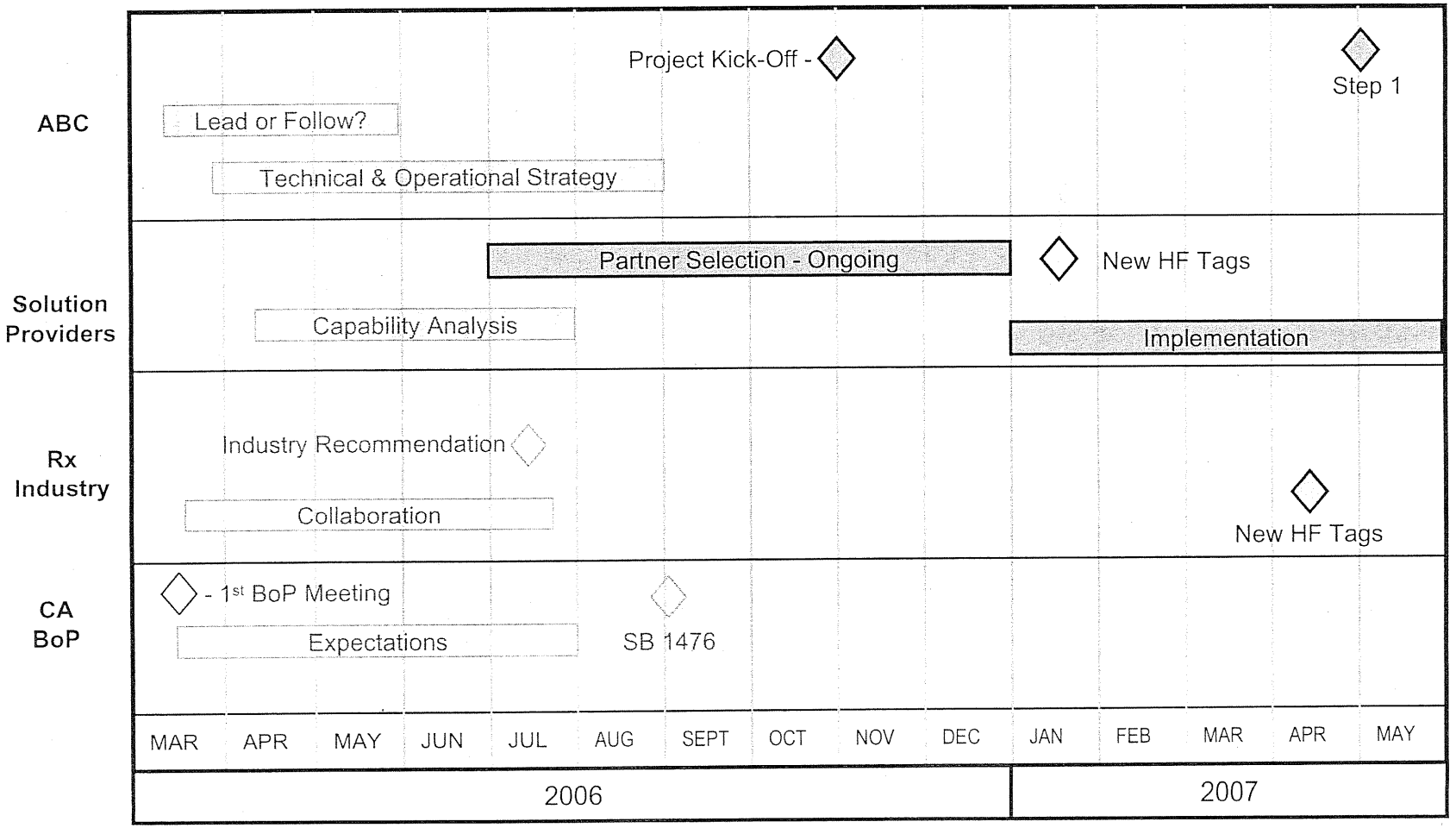
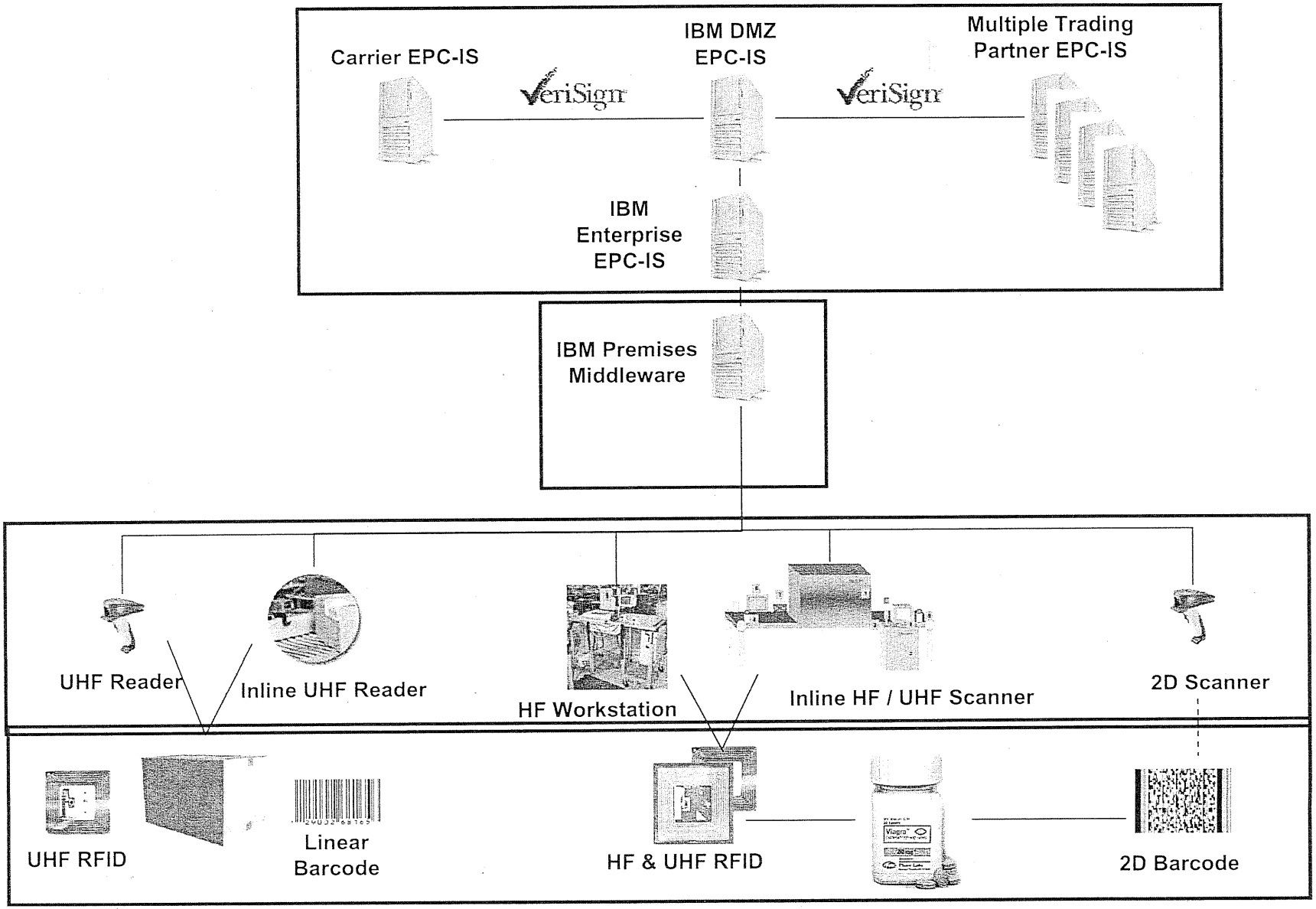
ABC's Plan to Pioneer:



AmerisourceBergen



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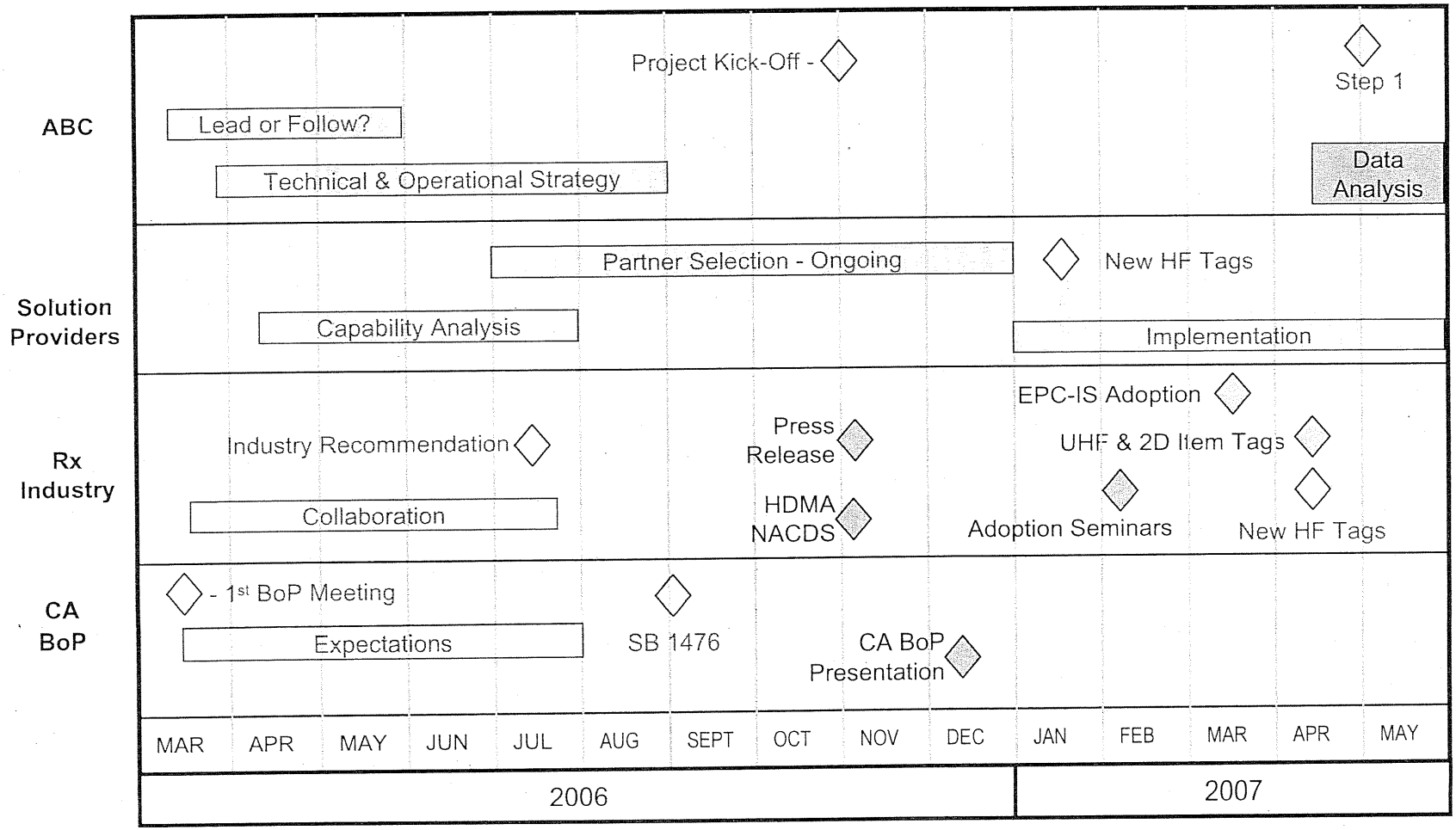
ABC's Plan to Collaborate:



ABC Appreciates CA BoP Approach:

- A Cautious Drive Toward Industry Action
- Electronic Track & Trace Includes Entire Supply Chain
- Unique Item Level Identification
- Non Prescriptive Technology
- Flexibility For Inference

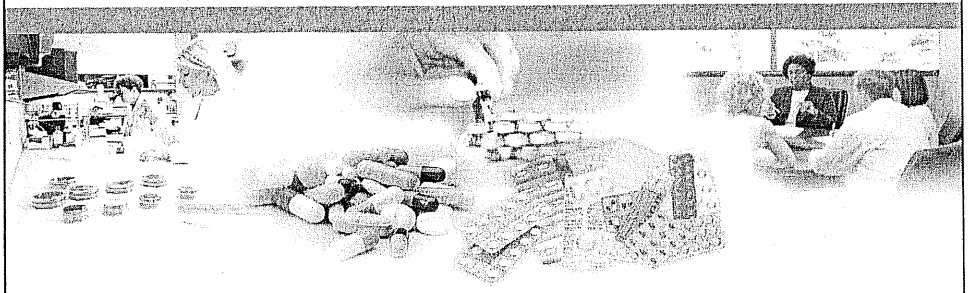
Questions?

Attachment 3

Presentation by Cardinal Health
December 12, 2006

CardinalHealth

December 12, 2006



Cardinal Health RFID Pilot Results

Julie Kuhn
Julie.Kuhn@cardinal.com

Agenda

- RFID Pilot
  - Overview
  - Results
  - Conclusion

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Pilot Overview

- Background
  - In 2004
    - Adoption of direct-distribution model
    - Develop an offering of authentication and track & trace technologies aimed at further securing supply-chain
    - Participated in first industry-wide RFID testing (Jumpstart 1)
  - In 2005
    - Collaborated with industry in RFID planning process (Jumpstart 2)
    - Began integrated effort between manufacturing / packaging and distribution businesses to develop an RFID solution
    - Solicited and received proposals from technology leaders
      - » Hardware
      - » Software (Middleware & Pedigree)
      - » Project Management
    - Met with various potential customers to gain knowledge on brand security/ RFID internal efforts
  - In 2006
    - Executed pilot

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RFID Pilot Objectives

- Optimize tagging operations
  - Considerations for inbound bulk drum tagged by manufacturer
  - Integrate printed component tag application into packaging operations
- Gather production data for internal and external publication
  - Determine read rate accuracy
  - Determine impact to current production processes & opportunities for improvement
  - Evaluate Cost impact of multiple facility scale-up
  - Establish infrastructure to provide feedback to manufacturers
  - Share results with legislative bodies regarding readability and possible effects on current cGMP/ regulatory practices.

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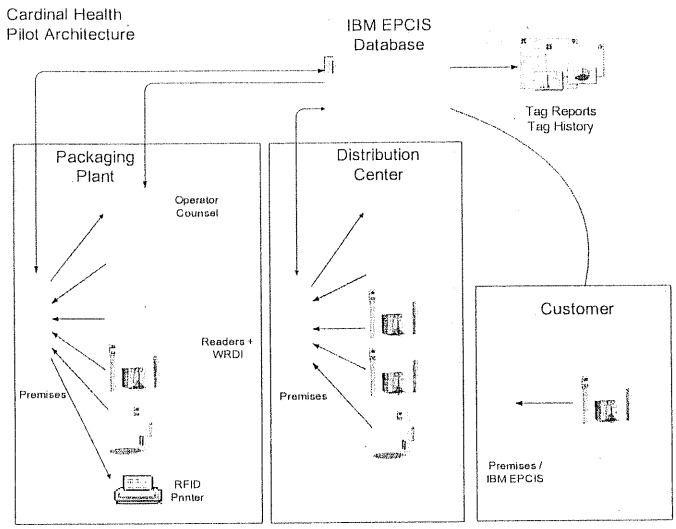
Architecture For Interoperability



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Definitions

- Aggregation: the collecting of individual units into a whole; a massing together or clustering of independent but similar units[1]
  - For example: 12 units = 1 case
    100 cases = 1 pallet
- Commission: the act of granting certain powers or authority to carry out a particular task or duty[2]
  - For example: RFID Tag is granted permission to carry data for a specific organization
- Inference: the act or process of deriving logical conclusions from premises known or assumed to be true; the act of reasoning from factual knowledge or evidence[3]
  - For example: If a case can be identified, contents are assumed to be known
- Interoperability: the ability to exchange and use information; the capability of being used or operated reciprocally[4]
  - For example: A manufacturer's system sends product information to a wholesaler in a generally accepted standard format

1. "aggregation." *Merriam-Webster's Dictionary of Law*. Merriam-Webster, Inc. 28 Nov. 2006 and The American Heritage® Stedman's Medical Dictionary. Copyright © 2002, 2001, 1995 by Houghton Mifflin Company. Published by Houghton Mifflin Company. (Dictionary.com)
2. "commission." *The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004. 28 Nov. 2006. (Dictionary.com)
3. "inference." *The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004. 28 Nov. 2006. (Dictionary.com)
4. "interoperability." *WordNet® 2.0*. Princeton University. 30 Nov. 2006 and "interoperability." *WordNet® 2.0*. Princeton University. 30 Nov. 2006. (Dictionary.com

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RFID Pilot Product Selection

- Non Major Pharma Company
- Product Diversity
  - Tablet Size/ Bottle Size
  - Unit Count
  - Round Bottle Vs Square
- Two Products
  - Rx A – Mid-tier manufacturer
    - Large tablet, 90 count unit, square bottle
    - Production run - 7/7/2006
  - Rx B - Mid-tier manufacturer
    - Small tablet, 90 count unit, round bottle
    - Production run - 7/20/2006

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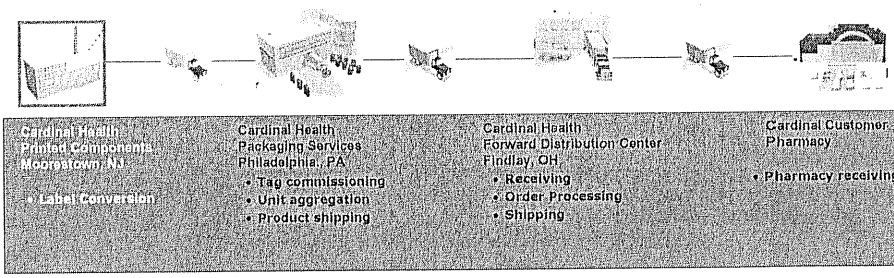
RFID Supply Chain Pilot

- Tagged product will flow through the following process:



- RFID Label Conversion
  - Print labels using existing label processes
    - Located at Cardinal printed component facility
    - Complete label printing and finishing capability
  - RFID tag insertion as a secondary operation

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RFID Supply Chain Pilot

- Tagged product will flow through the following process:

Cardinal Health Printed Components Moorestown, NJ • Label Conversion	Cardinal Health Packaging Services Philadelphia, PA • Tag commissioning • Unit aggregation • Product shipping	Cardinal Health Forward Distribution Center Findlay, OH • Receiving • Order Processing • Shipping	Cardinal Customer Pharmacy • Pharmacy receiving

- Product Packaging
  - Encoding in-line (read, write, read)
    - NDC & unique serial number is encoded
    - Production speed target – 120 bottles per minute
  - Aggregate units to cases simultaneously in production
  - Aggregate units to cases to pallets simultaneously - shrink wrap station
  - Read units and cases on outbound shipment

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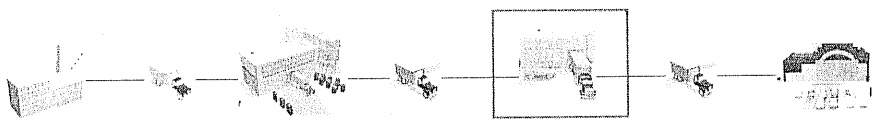
RFID Supply Chain Pilot

- Tagged product will flow through the following process:



Cardinal Health Printed Components Moorestown, NJ • Label Conversion	Cardinal Health Packaging Services Philadelphia, PA • Tag commissioning • Unit aggregation • Product shipping	Cardinal Health Forward Distribution Center Findlay, OH • Receiving • Order Processing • Shipping	Cardinal Customer Pharmacy • Pharmacy receiving

- Distribution
  - Read cases and units on pallet at receiving
  - Read cases and units in singular format on conveyor
  - Read units in totes ready for shipment
  - Read units on cart with 30 totes on outbound shipment at shrink wrap
  - Read units on cart on outbound shipment

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RFID Supply Chain Pilot

- Tagged product will flow through the following process:

Cardinal Health Printed Components Moorestown, NJ	Cardinal Health Packaging Services Philadelphia, PA	Cardinal Health Forward Distribution Center Findlay, OH	Cardinal Customer Pharmacy
• Label Conversion	• Tag commissioning • Unit aggregation • Product shipping	• Receiving • Order processing • Shipping	• Pharmacy receiving

- Pharmacy
  - Read units on inbound shipment (cart of 30 totes)

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RFID Pilot Results

Overall Results

Location	Item Level Read Rates		Case Level Read Rates	
	Rx A	Rx B	Rx A	Rx B
Unit encoding yield during packaging	97.7%	94.8%	N/A	N/A
Unit to case aggregation	96.9%	99.7%	91.8%	100%
Case to pallet aggregation	56.4%	80.8%	100%	99.7%
Packaging shipping	9.2%	14.3%	82.3%	100%
Distribution Center pallet receiving	7.8%	9.5%	76.3%	100%
Distribution Center case receiving	92.1%	97.1%	99.4%	100%
Distribution Center customer QC	N/A	99.6%	N/A	
Distribution Center turntable	N/A	64.2%	N/A	
Distribution Center shipping	N/A	47.1%	N/A	
Customer receiving	N/A	88.2%	N/A	

Represents best opportunity for RFID tag reads

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Read Rate Conclusions

- Overall
  - RFID tags can be successfully inlaid under existing FDA-approved pharmaceutical label stock
  - Packaging lines can be run at validated speeds while encoding and verifying RFID tag application
  - A single frequency (UHF) has the potential to work in critical points from pharmaceutical packaging to pharmacy receipt
  - No tag failures were encountered in any stage of the pilot

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Read Rate Conclusions

- Units
  - Item-level reads are not possible when cases are stacked on a pallet
  - Unit read rates within mixed totes are highly reliable (>99%) but have not achieved six sigma quality

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Read Rate Conclusions

- Cases
  - 100% read rates of case tags on a full pallet are potentially obtainable, but further testing is needed
  - Case read rates on a moving conveyor at shipping and receiving had read rates in excess of 99%

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Overall Conclusions

- RFID technology is feasible for "Tracking & Tracing" item level drugs in the pharmaceutical supply chain provided the following conditions and processes are met:
  - Item level reads are limited to individual each and case read processes with conditions managed to an ideal / consistent state
  - Inference is allowed to become an acceptable practice in the normal distribution process schemes
  - Full interoperability of systems from manufacturer to pharmacy
  - Barcode technology is used in a redundant / complementary strategy to allow "Track & Trace" in areas of privacy concerns, biologic product distribution and RFID tag failure
  - Implementation is measured and managed in a manner consistent with the technology capability, the compliance risk and the financial impact on individual stakeholders
  - Higher levels of collaboration are initiated among stakeholders to identify opportunities in the supply chain to significantly improve efficiencies and reduce costs

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